

# **Instructions for use**

# **PEDeDose**

**Clinical Decision Support Tool for  
Drug Dosages in Pediatrics for Healthcare  
Professionals**

## Table of contents

|          |  |           |
|----------|--|-----------|
| <b>1</b> | <b>General</b>                           | <b>4</b>  |
| 1.1      | Copyright                                | 4         |
| 1.2      | Accessibility                            | 5         |
| 1.3      | Login                                    | 5         |
| 1.4      | Language                                 | 5         |
| 1.5      | Technical information and requirements   | 6         |
| 1.6      | Intended purpose                         | 6         |
| 1.7      | Usage specification                      | 7         |
| 1.7.1    | Medical indication                       | 7         |
| 1.7.2    | Patient target groups                    | 7         |
| 1.7.3    | Intended user                            | 7         |
| a)       | End users                                | 7         |
| b)       | System integrators                       | 7         |
| c)       | Operators                                | 7         |
| 1.7.4    | User environment                         | 7         |
| 1.7.5    | Contraindications                        | 7         |
| 1.7.6    | Warnings, precautions and/or measures    | 8         |
| 1.7.7    | Training                                 | 8         |
| 1.8      | Residual risks                           | 8         |
| 1.9      | Clinical benefit                         | 8         |
| 1.10     | Technical performance                    | 8         |
| <b>2</b> | <b>Dosages</b>                           | <b>8</b>  |
| 2.1      | Age and weight                           | 9         |
| 2.2      | Dosages for preterm infants and neonates | 11        |
| 2.3      | Repetitions                              | 13        |
| 2.4      | Maximum dosage                           | 14        |
| 2.5      | Grade of recommendation                  | 15        |
| <b>3</b> | <b>Calculation</b>                       | <b>16</b> |
| 3.1      | Dose calculation                         | 16        |
| 3.2      | Child data: calculation basis            | 16        |
| 3.3      | Calculation of preterm infant doses      | 17        |
| <b>4</b> | <b>Web service</b>                       | <b>19</b> |

---

|           |  |           |
|-----------|--|-----------|
| 4.1       | Dose check                               | 19        |
| <b>5</b>  | <b>Products</b>                          | <b>20</b> |
| 5.1       | Products assigned to the dosage datasets | 20        |
| 5.2       | Product lists                            | 21        |
| <b>6</b>  | <b>Operating functions</b>               | <b>22</b> |
| 6.1       | Magnifying glass                         | 22        |
| 6.2       | Printing                                 | 22        |
| <b>7</b>  | <b>Detailed instructions for use</b>     | <b>22</b> |
| 7.1       | Child data                               | 22        |
| 7.2       | Search                                   | 23        |
| 7.2.1     | Substance search                         | 24        |
| 7.2.2     | Indication search                        | 31        |
| 7.2.3     | Product search                           | 36        |
| 7.3       | ATC code                                 | 41        |
| 7.4       | Abbreviations                            | 42        |
| 7.5       | Literature                               | 43        |
| <b>8</b>  | <b>Complaints and feedback</b>           | <b>44</b> |
| <b>9</b>  | <b>Contact information</b>               | <b>44</b> |
| 9.1       | General data                             | 44        |
| 9.2       | Web addresses PEdDose application        | 44        |
| <b>10</b> | <b>Primary label</b>                     | <b>45</b> |
| <b>11</b> | <b>Certifications</b>                    | <b>45</b> |
| <b>12</b> | <b>Annexes</b>                           | <b>45</b> |

## 1 General

The product PEDeDose is intended to support healthcare professionals in prescribing pediatric medication by providing patient-specific dosage information based on children's body weight, age, and body size, if relevant. Individual dosage recommendations can be calculated by using the integrated calculator. Dosage information is maintained in a database which is part of the product.

The product is not intended to replace the healthcare professional's decision on the choice and the dosage of the medication, but rather to support the healthcare professional in his or her decision by providing patient-specific data.

PEDeDose provides pediatric dosage information in three languages (German, French, English). Dosages are displayed via a search for substance, product (mainly products that are on the Swiss market), indication or ATC code. The information provided by PEDeDose (e.g. indications, dosages, «General Remarks») can be either «on label» or «off label use» concerning the relevant medication. When assessing whether it is an «on label use» or an «off label use», healthcare professionals must consult the product information. The final decision to use a medication «off label» remains with the attending healthcare professional. PEDeDose is available for healthcare professionals in European countries. For the Swiss market, additional (non-exhaustive) information (such as the preparation of the medication or application) of certain individual products is provided in German and French.

PEDeDose database does not claim to be exhaustive.

The latest version of the instructions for use is available at [www.pededose.ch](http://www.pededose.ch). It is the responsibility of the user to always have a printed, up-to-date version of the instructions for use. System integrators also receive the annexes I (Web service manual PEDeDose) and II (Deep links advanced manual PEDeDose) for the integration of the web service or the deep links into primary systems.

### 1.1 Copyright

Copyright © 2022-2027 PEDeus AG. All rights reserved.

No information contained in this document may be changed, copied, reproduced or transmitted by any means without the prior written consent of PEDeus. These instructions for use are intended for professional use only. They are not intended for public distribution and may not be used for commercial purposes. PEDeus assumes no liability for errors, mistakes or any damage caused by the use of a PEDeDose instructions for use document that has been modified without the prior written consent of PEDeus.

In the instructions for use PEDeus AG is referred to as PEDeus.

## 1.2 Accessibility

PEDeDose is intended for use by healthcare professionals. The access to the product is restricted by state-of-the-art login solutions (see 1.3).

Usually, PEDeDose is accessible 24 hours a day/365 days a year, unforeseen circumstances reserved. PEDeDose can only be used by registered users. Access is possible after registration with a personal e-mail address, or in Switzerland, also via swiss-rx-login.

Institutions may use access via IP address. Contact PEDeus for further information.

## 1.3 Login

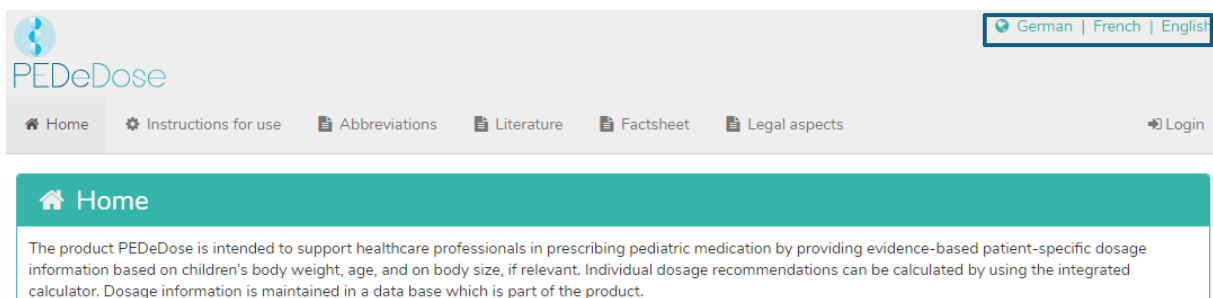
There are three different login processes: PEDeDose login, swiss-rx-login and IP-address login. With the PEDeDose and swiss-rx-login, the user must register upon first login and fill out a form about personal details. When logging in via the IP address, an institution receives direct access to the PEDeDose application for all end devices that use this IP address.

At PEDeDose the login via swiss-rx-login is limited to the user type "licensed academic professionals" on the basis of the personal data according to the medical profession register of the Federal Office of Public Health (Switzerland).

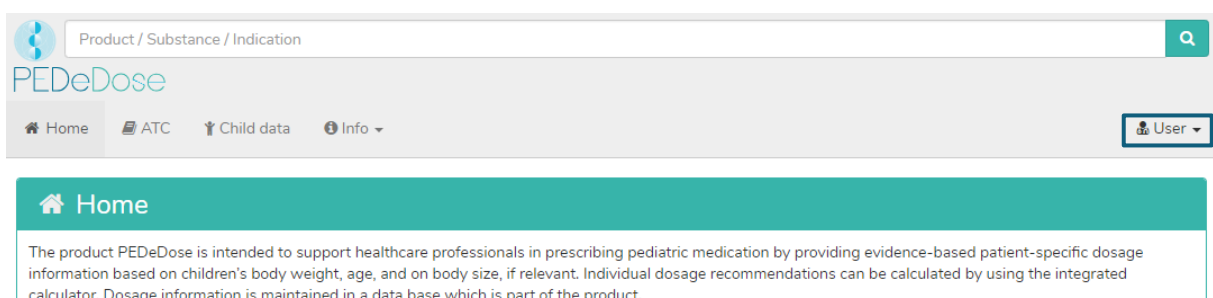
## 1.4 Language

PEDeDose is available in German, French and English.

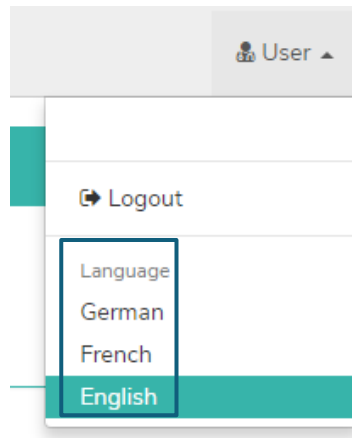
The language is selected on the top right of the home screen, see below:



After logging in, the language can be selected by clicking on the «User» button, see below:



The desired language is selected from the drop-down menu, see below:



## 1.5 Technical information and requirements

Minimum system requirements are 320 pixels (screen width) and 480 pixels (screen height). Switching to the mobile view takes place at less than 768 pixels. PEDeDose is designed for use on PCs, tablets and mobile phones (responsive design).

It is advisable for users to install an anti-virus software on their system.

PEDeDose runs on the most common internet browsers (e.g. Chrome, Edge, Safari, etc., in the respective most current versions).

The login remains active for one month if the user selects «Save Login» after registering and the browser does not automatically delete cookies after logging out. This does not apply to swiss-rx-login.

These instructions for use apply for PEDeDose versions from 2.4.0 to 2.4.99 or until a newer version is published. It replaces the previous version.

## 1.6 Intended purpose

The product PEDeDose, which includes the software module PEDeDose, supports healthcare professionals in the field of pediatric medication by providing patient-specific dosage recommendations based on children's body weight, age, and on body size, if applicable. Individual dosage recommendations can be calculated with the integrated calculator. The data for the dosage recommendations are maintained in a database, which is part of the module.

PEDeDose is not intended to control automated clinical processes. The final decision about the medication lies with the treating physician.

## **1.7 Usage specification**

### **1.7.1 Medical indication**

PEDeDose provides information on pediatric dosages and individual dosage recommendations for different pediatric indications.

### **1.7.2 Patient target groups**

PEDeDose is used in conjunction with pediatric patients, including neonates (term and preterm), infants, toddlers, children and adolescents.

No restrictions are defined with regard to the health status of patients.

### **1.7.3 Intended user**

#### **a) End users**

PEDeDose is intended exclusively for use by healthcare professionals (medical or pharmaceutical professionals, e.g. physicians, nurses, pharmacists).

#### **b) System integrators**

PEDeDose can be integrated by software developers into systems such as hospital information systems.

#### **c) Operators**

The administration of the PEDeDose data is exclusively carried out by the operators (PEDeus employees) who are medical or pharmaceutical professionals.

### **1.7.4 User environment**

PEDeDose is used either independently (standalone, website) or integrated into a primary system, such as a hospital information system.

The intended users have access to PEDeDose from different environments, including access from clinics/hospitals, ambulances, doctors' offices, pharmacies and from home.

### **1.7.5 Contraindications**

Not applicable

### **1.7.6 Warnings, precautions and/or measures**

The following warnings and precautions must be considered by the user.

- If a user enters incorrect data or data is entered in PEDeDose (unintentionally) by another person without the user's knowledge, the received output might be incorrect.
- It might happen that PEDeDose is temporarily unavailable or partially unavailable.
- The user may miss alerts for various reasons (e.g. work flow interruption, distraction).
- The information and data may not be fully visible on some (small) screens.
- As the system is IT-based, performance may be affected by cybercrime.

### **1.7.7 Training**

No specific training is necessary for the use of PEDeDose. Users are obliged to use PEDeDose in accordance with the instructions for use, which can be consulted at any time.

## **1.8 Residual risks**

All risks associated with PEDeDose have been reduced as far as possible to an acceptable level by appropriate measures (residual risks of intoxication due to overdose and inadequate or delayed therapeutic measures). The benefits of PEDeDose clearly outweigh these residual risks.

## **1.9 Clinical benefit**

The various functions of PEDeDose result in a benefit for the patient, which can be considered a secondary (indirect) clinical benefit. The clinical benefits include the reduction of dosing-related medication errors and the time reduction for calculating the dosage.

## **1.10 Technical performance**

Technical performance for medical device software includes the ability to generate the expected output data in an accurate, reliable and precise manner based on the input data. Technical performance was checked as part of the software verification of the applied software life cycle. All tests were met.

## **2 Dosages**

There is limited availability of clinical studies regarding dosages in children. The dosages displayed were carefully reviewed based on available literature and common practice of physicians at the University Children's Hospital Zurich or other children's hospitals/children's clinics. For better assessment of the dosages' accuracy, grades of recommendation (A-D) are displayed right next to the dosages (see chapter 2.5).



However, those dosages do not consider individual characteristics such as any impaired organ functions (kidney and liver insufficiency), drug interactions, obesity or genetic polymorphism. Due to advances in science and new findings, the data contained in PEDeDose is subject to continuous updating and improvement.

## 2.1 Age and weight

Each dosage in PEDeDose is based on age and/or weight. In premature infants and neonates, dosages may also depend on postnatal age (PNA).

The following table with examples explains how age and weight is to be interpreted

| Symbol/age or weight  | Explanation  |
|-----------------------|--|
| <x                    | below age/weight x   |
| ≥x                    | above or equal age/weight x  |
| a - b                 | from age/weight a (age/weight a is included) to age/weight b (age/weight b is not included)          |
| 10 D - 6 M            | from 10 days to 6 months minus 1 day   |
| 6 M - 12 Y            | from 6 months and 0 days to 11 years and 364 days  |
| ≥12 Y                 | from the 12 <sup>th</sup> birthday   |
| 1 D - 28 D            | from day 1 up to and including 27 days (preterm infants not included)                                |
| <28 D                 | neonates (preterm infants included) up to and including 27 days                                      |
| PMA 32 wk - PMA 36 wk | from 32 weeks and 0 days postmenstrual age up to and including 35 weeks and 6 days postmenstrual age |
| PNA <7 D              | up to and including a postnatal age of 6 days  |
| PNA ≥7 D              | from and including a postnatal age of 7 days   |
| <50 kg                | weight below 50 kg   |
| 5 - 40 kg             | from 5.00 to 39.99 kg  |

A dosage can be valid for an «age», «age AND weight», «age OR weight» or «weight», see the following table.

| Symbol/age or weight  | Explanation  |
|-----------------------|--|
| 1 Y - 18 Y            | valid for the age range 1 year to 17 years and 364 days; the weight is of no relevance |
| 1 Y - 18 Y and <50 kg | valid for the age range 1 year to 17 years and 364 days AND a weight below 50 kg       |
| 1 Y - 18 Y or <50 kg  | valid for the age range 1 year to 17 years and 364 days OR a weight below 50 kg        |
| ≥50 kg                | valid for a weight above or equal to 50 kg; the age is of no relevance                 |
| 5 - 40 kg             | valid for the range 5.00 kg to 39.99 kg; the age is of no relevance                    |

## 2.2 Dosages for preterm infants and neonates

Most dosages for preterm infants and neonates are based on age (resp. PMA) and/or weight, just like the dosages for older children.

However, some dosages for preterm infants and neonates also refer to postnatal age (PNA), usually in addition to postmenstrual age and/or weight. The following picture illustrates these relationships using the example of indomethacin, i.v., in patent ductus arteriosus.

| Substance               |        | Indomethacin                   |             |                |                 |                       |                 |                |   |     |     |
|-------------------------|--------|--------------------------------|-------------|----------------|-----------------|-----------------------|-----------------|----------------|---|-----|-----|
| Indication              |        | patent ductus arteriosus (PDA) |             |                |                 |                       |                 |                |   |     |     |
| Route of administration |        | IV, parenteral                 |             |                |                 |                       |                 |                |   |     |     |
| Calculated dose         |        |                                |             |                |                 |                       |                 |                |   |     |     |
| General doses           |        |                                |             |                |                 |                       |                 |                |   |     |     |
| Age/PMA                 | Weight | PNA                            | Application | Type of dose   | Dose            | Number of repetitions | Max single dose | Max daily dose | Remarks   | GR  | Ref |
| PMA <28 wk              |        |                                | IV          |                | 0.1 mg/kg/dose  |                       |                 |                | 3 doses at intervals of 12-24 h each; by inf over 20-30 min | (A) |     |
| PMA ≥28 wk and <1.75 kg |        |                                | IV          | 1st dose       | 0.2 mg/kg/dose  |                       |                 |                | at time 0 h, 2nd dose after 12-24 h; by inf over 20-30 min  | (A) |     |
| PMA ≥28 wk and <1.75 kg |        | and PNA <2 D                   | IV          | 2nd + 3rd dose | 0.1 mg/kg/dose  |                       |                 |                | at intervals of 12-24 h each; by inf over 20-30 min         | (A) |     |
| PMA ≥28 wk and <1.75 kg |        | and PNA 2 - 7 D                | IV          | 2nd + 3rd dose | 0.2 mg/kg/dose  |                       |                 |                | at intervals of 12-24 h each; by inf over 20-30 min         | (A) |     |
| PMA ≥28 wk and <1.75 kg |        | and PNA 7 - 28 D               | IV          | 2nd + 3rd dose | 0.25 mg/kg/dose |                       |                 |                | at intervals of 12-24 h each; by inf over 20-30 min         | (A) |     |

If postnatal age (PNA) is applicable for calculating the dosage for a child, the following combinations are possible:

| Age/PMA, PNA, weight              | Explanation  |
|-----------------------------------|--|
| PMA <40 wk and PNA <8 D           | valid for a preterm infant with a postmenstrual age below 40 weeks and a postnatal age below 8 days  |
| 0 - 8 D and PNA ≥8 D              | valid for a former preterm infant with a corrected age of 0 to including 7 days and a postnatal age of 8 days or more                      |
| 0 - 8 D and PNA <8 D              | valid for a term infant with an age of less than 8 days  |
| PMA 32 wk - 36 wk and <2 kg       | valid for a preterm infant with a postmenstrual age of 32 weeks up to and including 35 weeks and 6 days and weighing less than 2.000 kg    |
| PMA <40 wk and <2 kg and PNA <7 D | valid for a preterm infant with a postmenstrual age below 40 weeks and a weight below 2.000 kg and a postnatal age below 7 days            |
| PNA <8 D                          | valid for a neonate (preterm or term) with a postnatal age of less than 8 days; the postmenstrual age as well as the weight are irrelevant |

The following ages are used in connection with preterm birth:

- postnatal age (PNA) = number of days of life from birth
- postmenstrual age (PMA) = sum of gestational age at birth and postnatal age (used in PEDeDose only for preterm infants)
- chronological age (chronA) = number of days of life (resp. months, years) from birth
- corrected age (corrA) = chronological age minus the weeks missing to complete 40 weeks of gestation (= chronological age plus gestational age at birth minus 40 weeks)

Preterm birth is when the child is born before 37 weeks of gestation. For dosage calculation purposes, neonates born before 37 weeks of gestation are considered preterm up to a postmenstrual age of 39 weeks and 6 days. From a postmenstrual age of 40 weeks and 0 days, they are considered term infants. After that, the corrected age is used. The calculation according to the corrected age is

maintained until the end of the 36<sup>th</sup> month (chronological age), after which the dosage is calculated according to the chronological age.

The following different «ages» may apply to the age information in the age/PMA column on the website:

- postmenstrual age (PMA): for preterm infants
- corrected age (corrA): for former preterm infants (PMA  $\geq$ 40 wk up to 36 months)
- chronological age (chronA): for term and former preterm infants  $\geq$ 36 months

## 2.3 Repetitions

The number of daily repetitions refers to the number of doses over 24 hours in equally large time intervals. The following table shows with some examples how the number of repetitions [Number of repetitions] is to be interpreted:

| Number of repetitions | Time interval                   |
|-----------------------|---------------------------------|
| 1 x daily             | one dose every 24 h             |
| 2 x daily             | one dose every 12 h             |
| 3 - 4 x daily         | one dose every 6 h to every 8 h |
| 6 x daily             | one dose every 4 h              |

## 2.4 Maximum dosage

In the database, maximum single and/or daily dosages are indicated in some cases. The interpretation of maximum dosages is difficult with children. If the main dosage is given per kg body weight, whereas the maximum dosage is given as a fixed dosage without reference to body weight, this maximum dosage must be interpreted as follows: The main dosage is valid up to the body weight («limit») where the maximum dosage is reached. If the child weighs less than this «limit», the maximum dosage must not be applied. If the child weighs more, it will no longer be dosed per kg of body weight, but the maximum dosage is administered.

The following is an example of the explanations above:

| Substance | Age                    | Dosage        | Max. single dose |
|-----------|------------------------|---------------|------------------|
| X         | 28 D – 18 Y and <50 kg | 10 mg/kg/dose | 400 mg/dose      |

If a child weighs <40 kg, the maximum single dose must not be administered, but the dosage must be calculated using the formula 'body weight in kg x dosage in mg/kg/dose'. For a child weighing 20 kg, this results in a dosage of 200 mg/dose.

If a child weighs  $\geq 40$  kg and <50 kg, the maximum single dose of 400 mg/dose is administered (40 kg x 10 mg/kg/dose). For children weighing more than 40 kg, no calculation takes place anymore, as the maximum single dose has been reached and must not be exceeded.

The calculator in PEdDose considers maximum dosages in the calculations.

## 2.5 Grade of recommendation

The grade of recommendation refers to the main dosage, not to maximum single or daily dosage. The classification is divided into four different grades, from A to D. Should there be multiple references, the grade of recommendation refers to the reference with the highest grade.

| Grade of recommendation | Explanation  |
|-------------------------|--|
| A                       | Systematic review of randomised controlled trials (RCT); well-planned, single randomised controlled studies; all-or-nothing principle (approval by the Swiss authorities since 01/01/2011)                         |
| (A)                     | Systematic review of randomised controlled trials (RCT); well-planned, single randomised controlled studies; all-or-nothing principle (approval by the Swiss authorities before 2011)                              |
| B                       | Systematic review of well-planned cohort studies; well-planned single cohort studies (and RCT with modest follow-up); outcome-research study; systematic review of case-control-studies; single case-control study |
| C                       | Case series; bad cohort and case-control studies   |
| D                       | Expert's opinion without explicit clinical assessment; physiological models; comparisons; principles; few case studies   |

If a dosage specification is not within the literature dosage, but a partial aspect is deviating, the grade of recommendation is lowered by one level.

### 3 Calculation

If the user runs the PEDeDose version without calculator, this chapter will not apply.

#### 3.1 Dose calculation

The PEDeDose website allows the calculation of doses for a child after entering date of birth, body weight and - if necessary - height. With preterm infants, also the gestational age at birth is entered. For dosages that relate to the body surface of a child, the body surface is estimated based on the Mosteller formula. A few datasets do not permit dosage calculation. In this case, a corresponding warning message is displayed.

**▲ No individual dose is calculated for this (these) dosing line(s).**

#### 3.2 Child data: calculation basis

The following values are allowed for the weight and height of the child (see table below):

|                    | Minimum | Maximum |
|--------------------|---------|---------|
| <b>Weight [kg]</b> | 0.25    | 200     |
| <b>Height [cm]</b> | 20      | 250     |

If a value outside the limits is entered, an error message is displayed.

Child data entries are checked for plausibility based on percentile curves<sup>1, 2</sup> (weight and height). A warning is shown in case of weight and/or height below the 1<sup>st</sup> or above the 99<sup>th</sup> percentile. In preterm infants, a warning is shown in case of weight and/or height below the 3<sup>rd</sup> or above the 97<sup>th</sup> percentile.

The dosage in obese children is complex; various factors/criteria have to be considered. For this reason, PEDeDose allows the calculation of the BMI, which gives the user an indication of whether they need to further clarify the dosage. Entering weight and height permits the calculator to calculate the child's BMI, which will be displayed below the calculated dosage. Please consult the factsheet «Drug dosing in overweight children» ([www.pededose.ch](http://www.pededose.ch), «Info»).

Child data is saved for as long as the user is logged in. If the user logs out or closes the browser, the child data is deleted.

<sup>1</sup> Braegger C et al. New Swiss growth charts. *Paediatrica* 2011; 22(1): 9-11.

<sup>2</sup> Pädiatrie Schweiz. Recommendation regarding the request to adapt the current Swiss growth charts. October 2020. Online access 08/2021.



### 3.3 Calculation of preterm infant doses

In preterm infants, the gestational age at birth (weeks and days) must be additionally entered with the child data.

Preterm infants are born prior to the completed 37<sup>th</sup> week of pregnancy. For dosage calculation, they remain preterm infants until the postmenstrual age (PMA) of 39 weeks and 6 days is reached. They change into neonatal age for dosage calculation from 40 weeks and 0 days postmenstrual age (PMA). After that, the corrected age applies. The calculation according to corrected age (corrA) is maintained until the end of the 36<sup>th</sup> month (chronological age (chronA)), then the dosage is calculated based on chronological age.

An exception to this rule are active vaccines; these are calculated and displayed according to the chronological age (chronA).

Here are some examples:

A preterm infant born at a gestational age of 32 weeks (GA 32 0/7 WOP) 2 days ago (PNA 2 D), i.e. the current postmenstrual age is 32 weeks and 2 days (PMA 32 2/7 wk):

| Substance               |               | Acetaminophen (Paracetamol)                 |             |              |                 |                       |                 |                |         |           |     |     |
|-------------------------|---------------|---|-------------|--------------|-----------------|-----------------------|-----------------|----------------|---------|-----------|-----|-----|
| Indication              |               | analgesia (mild pain, pain score ≤3), fever |             |              |                 |                       |                 |                |         |           |     |     |
| Route of administration |               | PO, liquid                                  |             |              |                 |                       |                 |                |         |           |     |     |
| Calculated dose         |               |   |             |              |                 |                       |                 |                |         |           |     |     |
| PMA                     | Weight        | PNA   | Application | Type of dose | Dose            | Number of repetitions | Max single dose | Max daily dose | Remarks | GR        | Ref |     |
| PMA 32 2/7 wk           | 1750 g        | 2 D   | PO          |              | 18 - 26 mg/dose | 3 - 4 x daily         |                 | 105 mg/day     |         | D         |     |     |
|                         | Date of birth | 03.12.2022                                  | Weight      | 1750 g       | PI              | Yes                   | GA              | 32 0/7 WOP     | PMA     | 32 2/7 wk | PNA | 2 D |

A preterm infant born at a gestational age of 35 weeks and 3 days (GA 35 3/7 WOP) 5 weeks ago (PNA 5 wk), i.e. the current corrected age is 3 D (corrA 3 D):

| Substance               |               | Acetaminophen (Paracetamol)                 |             |              |                 |                       |                 |                |         |     |     |      |
|-------------------------|---------------|---|-------------|--------------|-----------------|-----------------------|-----------------|----------------|---------|-----|-----|------|
| Indication              |               | analgesia (mild pain, pain score ≤3), fever |             |              |                 |                       |                 |                |         |     |     |      |
| Route of administration |               | PO, liquid                                  |             |              |                 |                       |                 |                |         |     |     |      |
| Calculated dose         |               |   |             |              |                 |                       |                 |                |         |     |     |      |
| Age                     | Weight        | PNA   | Application | Type of dose | Dose            | Number of repetitions | Max single dose | Max daily dose | Remarks | GR  | Ref |      |
| 3 D                     | 2800 g        |   | PO          |              | 28 - 42 mg/dose | 3 - 4 x daily         |                 | 168 mg/day     |         | D   |     |      |
|                         | Date of birth | 31.10.2022                                  | Weight      | 2800 g       | PI              | Yes                   | GA              | 35 3/7 WOP     | corrA   | 3 D | PNA | 5 wk |

A former preterm infant (GA 35 3/7 WOP) born 4 years ago, i.e. the current chronological age is 4 years (chronA 4 Y 0 mth):

| Substance                                   |               |            |             |              |                   |                       |                 |                |         |           |     |
|---|---------------|------------|-------------|--------------|-------------------|-----------------------|-----------------|----------------|---------|-----------|-----|
| Acetaminophen (Paracetamol)                 |               |            |             |              |                   |                       |                 |                |         |           |     |
| Indication                                  |               |            |             |              |                   |                       |                 |                |         |           |     |
| analgesia (mild pain, pain score ≤3), fever |               |            |             |              |                   |                       |                 |                |         |           |     |
| Route of administration                     |               |            |             |              |                   |                       |                 |                |         |           |     |
| PO, liquid                                  |               |            |             |              |                   |                       |                 |                |         |           |     |
| Calculated dose                             |               |            |             |              |                   |                       |                 |                |         |           |     |
| Age   | Weight        | PNA        | Application | Type of dose | Dose              | Number of repetitions | Max single dose | Max daily dose | Remarks | GR        | Ref |
| 4 Y 0 mth                                   | 12 kg         |            | PO          |              | 180 - 240 mg/dose | 4 x daily             |                 |                |         | C         |     |
|   | Date of birth | 05.12.2018 | Weight      | 12 kg        | PI                | Yes                   | GA              | 35 3/7 WOP     | chronA  | 4 Y 0 mth |     |

## 4 Web service

This part of the instructions for use is for users of the web service. The web service provides access to PEDeDose via integration in a clinical information system, in a medical practice or pharmacy software. The web service allows the user to either calculate a dosage after entering the substance or product or to check a self-selected dosage.

The user of the web service is responsible for the timeliness of the entered child data. All alerts and warnings provided by PEDeDose must be displayed to the user in the clinical information system, in a medical practice or pharmacy software.

System integrators can find more information about the integration via web service in the Annex I Web service manual PEDeDose.

### 4.1 Dose check

The web service allows the user to check a self-selected dosage and indicates the deviation from the calculated dosage in percent. If the defined, active substance-dependent tolerance – classified according to drugs with broad or narrow therapeutic index – is exceeded or not reached by the deviation between the self-selected and the calculated dosage, the user receives a warning together with the deviation in percent of the active substance used, see table below.

| Active substance         | Limit | Okay /green* | Warning/orange* | Dangerous/red*  | Toxic/black* |
|--------------------------|-------|--------------|-----------------|---|--------------|
| Broad therapeutic index  | Below | 90 - 111%    | 80 - 90%        | <80%  |              |
|                          | Above |              | 111 - 125%      | Maximum dosage OR >125% (if no maximum dosage is available) | >300%        |
| Narrow therapeutic index | Below | 95 - 105%    | 90 - 95%        | <90%  |              |
|                          | Above |              | 105 - 111%      | Maximum dosage OR >111% (if no maximum dosage is available) | >150%        |

\* The status/colours and/or symbols are provided by the clinical information system, the medical practice or pharmacy software; the last column («Toxic/black») may be shown together with «Dangerous/red».

If PEDeDose is specified in ranges, the highest (for upper limits) or the lowest value (for lower limits) is used for the tolerance calculation, respectively.

The dose check is not designed to detect over- or underdosages when several identical or similar substances are being prescribed to a child.

In addition to the single doses that remain constant throughout the day, it is also possible to check dosages at which the single doses are administered in different amounts throughout the day. The number of single doses per day corresponds to the number of repetitions over 24 hours in equal time intervals: 1 single dose = 1 x daily (every 24 h); 2 single doses = 2 x daily (= every 12 h); 3 single doses = 3 x daily (= every 8 h) etc.

## 5 Products

### 5.1 Products assigned to the dosage datasets

Products that match the dosages are assigned to the individual dosage datasets. The products are selected according to the following criteria:

- **Excipients:** The excipients in a product are checked. If a product contains unsuitable excipients, this is noted under the «Product specific remarks», including the age up to which the excipient in question is unsuitable.
- **Approval according to product information:** If possible, products are linked that are approved for the indication and the age of the corresponding dosage dataset. If no approved products are available, off-label links are made, always taking into account further criteria such as excipients, contraindications, etc.
- **Dosage strength:** Usually, products are assigned to the dosage datasets which, with regard to their dosage, are in a range covering half of the lowest dosage range to twice the highest dosage range. In the case of solid oral products, divisibility and crushability are taken into account in the assignment.

It is up to the healthcare professional to decide which product to use with an individual patient.

## 5.2 Product lists

For institutions, product lists can be created for display in PEDeDose. For this purpose, the institution will send PEDeus a list of products to be labelled by individual arrangement. These products will be marked with a star in the respective institution after processing by PEDeus. This may be used for example to display the institution's internal products or favourites in PEDeDose (see figure below for products Ibuprofen, oral, liquid: One product is marked with a star).

| 9 Products ▾                        |           |                   |
|-------------------------------------|-----------|-------------------|
| ALGIFOR Dolo forte Susp 200 mg/5ml  | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo forte Susp 400 mg/10ml | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior 150 mg/7.5ml    | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior Susp 100 mg/5ml | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Junior Susp 100 mg/5ml ★    | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Liquid Caps 400 mg          | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR-L Filmtabl 200 mg           | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR-L forte Filmtabl 400 mg     | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR-L Gran 200 mg               | Ibuprofen | <a href="#">↗</a> |

In the list of active substances, a star indicates whether an active substance has links to labelled products.

| Search results for <b>ibuprofen</b> |  |
|-------------------------------------|--|
| 1 Substance ▾                       |  |
| ibuprofen ★                         |  |
| 7 Products ▾                        |  |

## 6 Operating functions

### 6.1 Magnifying glass

If a magnifying glass is visible next to a search term, click on the symbol to return to this search term or select this search term (see in the example below next to «Substance Ibuprofen»).



The screenshot shows a search bar with the text "Substance Ibuprofen" and a magnifying glass icon. Below the search bar, there are two sections: "Indications" and "patent ductus arteriosus (PDA)". The "Indications" section lists "analgesia (mild / moderate pain), fever, perioperative analgesia".

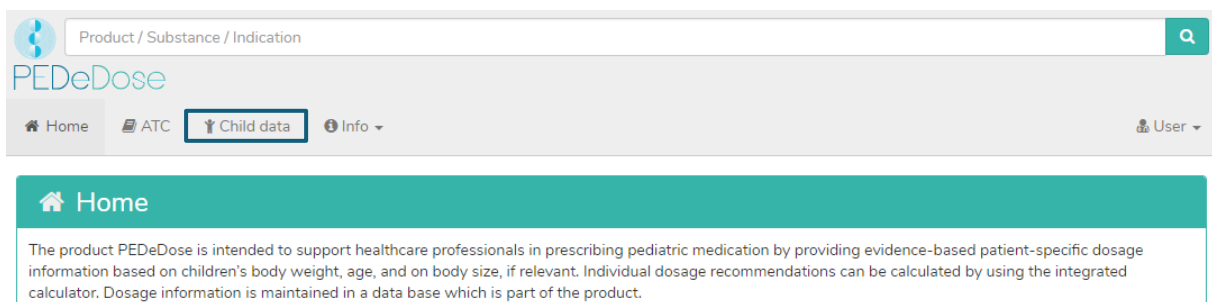
### 6.2 Printing

If required, an extract can be printed from PEDeDose with a conventional printer (e.g. calculated dosages). It is recommended to generate a printed extract for a single application only.

## 7 Detailed instructions for use

### 7.1 Child data

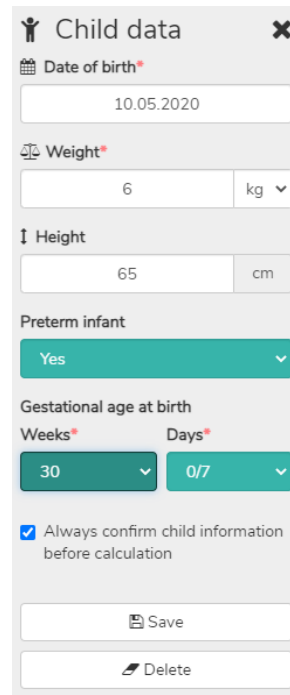
Clicking on «Child data» opens a window in which you can enter information concerning the child for whom a drug dosage is to be prescribed.



The screenshot shows the PEDeDose navigation menu. The search bar contains "Product / Substance / Indication". The navigation bar includes "Home", "ATC", "Child data" (highlighted with a red box), and "Info". The "Child data" button has a magnifying glass icon. The "Home" button has a house icon. The "Info" button has a downward arrow. The "User" button has a user icon and a downward arrow. Below the navigation bar, there is a section titled "Home" with a house icon. The text below "Home" reads: "The product PEDeDose is intended to support healthcare professionals in prescribing pediatric medication by providing evidence-based patient-specific dosage information based on children's body weight, age, and on body size, if relevant. Individual dosage recommendations can be calculated by using the integrated calculator. Dosage information is maintained in a data base which is part of the product."

For individual dosage calculation, the following information is entered (the red asterisk marks the mandatory fields):

- Date of birth
- Weight [kg or g]
- Height ([cm], only for drugs where the body surface is necessary for dose calculation or as a prerequisite for the calculation of the BMI)
- Preterm infant (yes or no)
- Gestational age at birth ([«Weeks» and «Days»], only after clicking «Yes» for Preterm infant)



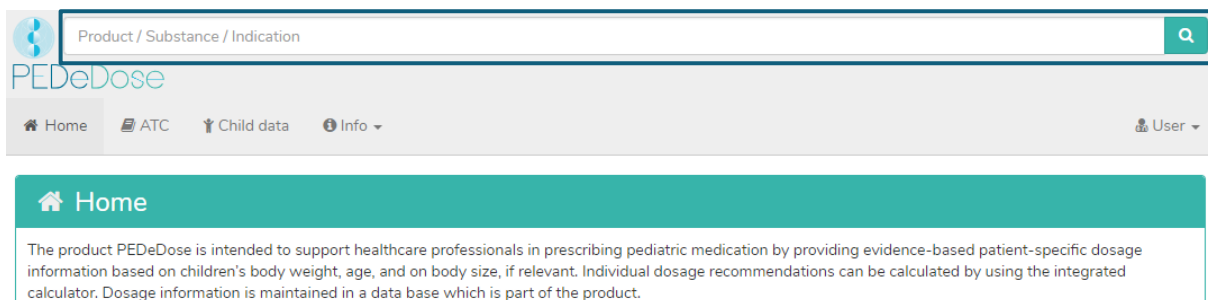
For preterm infants, select «Yes» in the field «Preterm infant». Subsequently, the gestational age at birth is entered in weeks and days (see chapter 3.3).

By checking the box below, the user can choose to be asked before each new calculation as to whether they wish to proceed with the previously entered child data («Always confirm child information before calculation»). For systems accessing PEDeDose via deep links or via web service, this option can be turned off so that the user does not have to confirm the child information before the calculation. The users of the corresponding systems must be aware that PEDeDose assumes that the child information sent is correct and has already been verified by the user in the system accessing PEDeDose.

The entered data is saved by clicking on the «Save» button or deleted by clicking on the «Delete» button.

## 7.2 Search

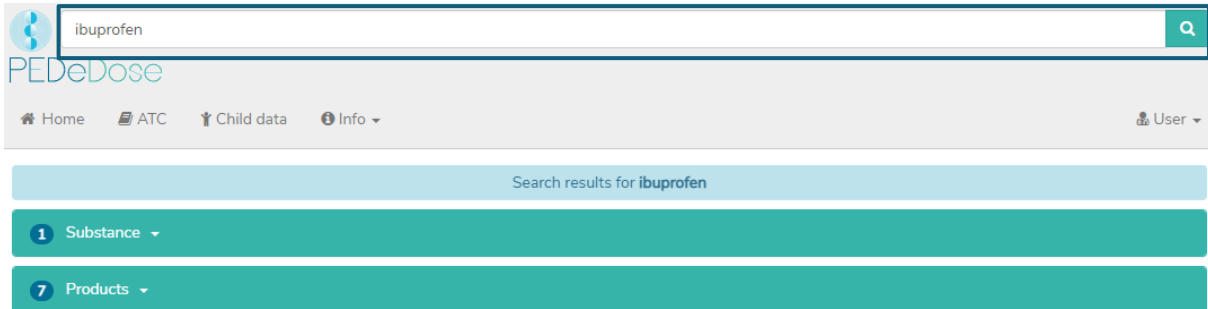
In the «Search» field, either a substance name, a drug indication or a product name can be entered; at least three letters or two letters (characters) and «%» must be entered. The search function is not case-sensitive.



## 7.2.1 Substance search

### 7.2.1.1 Substance

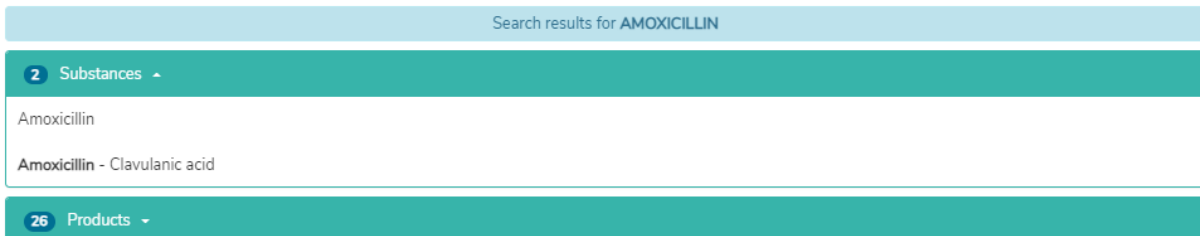
The substance name is entered in the «Search» field (e.g. «ibuprofen»).



The screenshot shows the PEDeDose search interface. At the top, there is a search bar containing the text 'ibuprofen' and a magnifying glass icon. Below the search bar, the PEDeDose logo is visible. A navigation bar includes links for Home, ATC, Child data, and Info, along with a User profile icon. Below the navigation bar, a light blue header indicates 'Search results for ibuprofen'. Two teal-colored buttons are displayed: '1 Substance' and '7 Products', both with dropdown arrows.

The search results are displayed below the «Search» field. For the example «ibuprofen», the search returns one substance and seven products as a result.

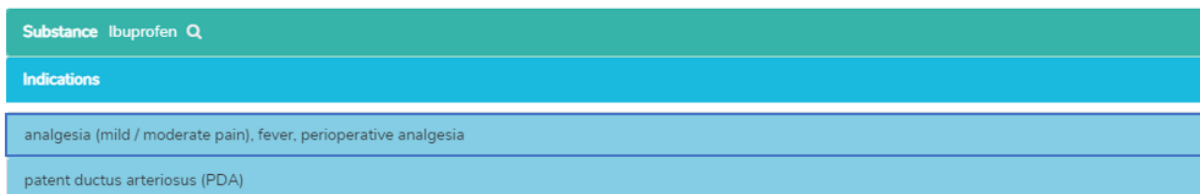
If the dosage only refers to one active ingredient of an active ingredient combination, this active ingredient is displayed in bold. In the example below, amoxicillin is displayed in bold for the active ingredient combination amoxicillin - clavulanic acid, since the dosage in PEDeDose refers to amoxicillin and not to the combination amoxicillin - clavulanic acid.



The screenshot shows the PEDeDose search interface for 'AMOXICILLIN'. A light blue header indicates 'Search results for AMOXICILLIN'. Below this, a teal button shows '2 Substances'. A white box lists the search results: 'Amoxicillin' and 'Amoxicillin - Clavulanic acid'. The word 'Amoxicillin' in the second entry is bolded. Below the results box, another teal button shows '26 Products'.

### 7.2.1.2 Indication

By clicking on the field «Substance» and then on the substance («Ibuprofen»), the «Indication» field is opened (two indications for the selected example):



The screenshot shows the PEDeDose interface for the substance 'Ibuprofen'. At the top, a teal bar displays 'Substance Ibuprofen' with a magnifying glass icon. Below this, a blue bar is labeled 'Indications'. Two light blue bars list the indications: 'analgesia (mild / moderate pain), fever, perioperative analgesia' and 'patent ductus arteriosus (PDA)'.



### 7.2.1.3 Application

Clicking on an indication (in this case «analgesia (mild / moderate pain), fever, perioperative analgesia») opens the selection of application (route of administrations/galenic groups), see below.

| Substance                         | Ibuprofen  |
|-----------------------------------|--|
| Indications                       | analgesia (mild / moderate pain), fever, perioperative analgesia |
| PO, liquid                        |  |
| PO, effervescent and liquid forms |  |
| PO, tablets, dragees, capsules    |  |
| REC                               |  |
| patent ductus arteriosus (PDA)    |  |

### 7.2.1.4 General doses

Clicking on an application (i.e. «PO, liquid») opens the «General doses» window, see below.

If there are substance specific remarks for the selected active substance, these are displayed below the «General doses»; see below (they may include for example dosage notes, attention remarks, contraindications).

| Substance                  | Ibuprofen  |     |             |              |                   |                       |                 |                |         |     |     |
|----------------------------|--|-----|-------------|--------------|-------------------|-----------------------|-----------------|----------------|---------|-----|-----|
| Indication                 | analgesia (mild / moderate pain), fever, perioperative analgesia   |     |             |              |                   |                       |                 |                |         |     |     |
| Route of administration    | PO, liquid   |     |             |              |                   |                       |                 |                |         |     |     |
| Calculated dose            |  |     |             |              |                   |                       |                 |                |         |     |     |
| General doses              |  |     |             |              |                   |                       |                 |                |         |     |     |
| Age/PMA                    | Weight   | PNA | Application | Type of dose | Dose              | Number of repetitions | Max single dose | Max daily dose | Remarks | GR  | Ref |
| 3 mth - 6 mth and ≥5 kg    |  |     | PO          |              | 7 - 10 mg/kg/dose | 3 x daily             |                 | 30 mg/kg/day   |         | B   |     |
| 3 mth - 6 mth and ≥5 kg    |  |     | PO          |              | 5 - 7 mg/kg/dose  | 4 x daily             |                 | 30 mg/kg/day   |         | B   |     |
| 6 mth - 18 Y and 5 - 40 kg |  |     | PO          |              | 7 - 10 mg/kg/dose | 3 x daily             |                 | 30 mg/kg/day   |         | (A) |     |
| 6 mth - 18 Y and 5 - 40 kg |  |     | PO          |              | 5 - 7 mg/kg/dose  | 4 x daily             |                 | 30 mg/kg/day   |         | (A) |     |
| <18 Y and 40 - 50 kg       |  |     | PO          |              | 200 - 400 mg/dose | 3 - 4 x daily         |                 |                |         | (A) |     |
| ≥18 Y or ≥50 kg            |  |     | PO          |              | 400 - 600 mg/dose | 3 - 4 x daily         |                 | 2400 mg/day    |         | A   |     |
| Substance specific remarks |  |     |             |              |                   |                       |                 |                |         |     |     |
| <b>attention</b>           | A good hydration of the patient is important. [152 (Algifor, 11/2019), 185]  |     |             |              |                   |                       |                 |                |         |     |     |
| <b>Qe-value</b>            | 1 [58 (04/2019)]   |     |             |              |                   |                       |                 |                |         |     |     |
| <b>contraindications</b>   | infants <3 mth and <5 kg (indication fever, analgesia) [185]; dehydration, active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, HI or RI, hereditary fructose intolerance (sorbitol), patients under anticoagulatory therapy with acetylsalicylic acid [7, 152 (Algifor, 04/2019)] |     |             |              |                   |                       |                 |                |         |     |     |
| <b>interactions</b>        | other NSAID, glucocorticoids, oral anticoagulants, digoxin, phenytoin, methotrexate, baclofen, quinolones, low-dose acetylsalicylic acid (can be substituted by diclofenac) [7, 122, 152 (Algifor, 04/2019)]   |     |             |              |                   |                       |                 |                |         |     |     |
| 11 Products in Switzerland |  |     |             |              |                   |                       |                 |                |         |     |     |

The «General doses» window provides the following information:


| Information           | Explanation   |
|-----------------------|---|
| Age/PMA               | Age of the child for whom the dosage is recommended<br>(PMA: postmenstrual age, in case of a dosage for a preterm infant)   |
| Weight                | Weight of the child for whom the dosage is recommended  |
| PNA                   | Postnatal age (only relevant for neonates and preterm infants)  |
| Application           | Route of administration (REC, PO, IV, IM, etc.)   |
| Type of dose          | Loading dose, maintenance dose, etc.  |
| Dose                  | Usually in mg/kg/dose, for adults often mg/dose   |
| Number of repetitions | Number of repetitions per day (2 x daily, 3 x daily, etc.)  |
| Max single dose       | Maximal dose per single administration  |
| Max daily dose        | Maximal dose per day  |
| Remarks               | Remarks regarding dosage, application, etc.   |
| GR                    | Grade of recommendation (see chapter 2.5)   |
| Ref                   | Reference (number of reference on which the dosage is based), see «Literature» (chapter 7.5) for the reference list. The «book symbol» works as a mouse-over button (does not work on tablets and smartphones. In these cases, the references are directly accessible). |


### 7.2.1.5 Calculated dose

A click on «Calculated dose» opens a window with the individually calculated dose for the child whose data have been entered in the field «Child data». (There are two dosage datasets in the example below because there are two different numbers of repetitions (3 x daily and 4 x daily).)



The dataset of the individually calculated dose shows the age and weight of the child for whom the dose has been calculated (in the example below «3 Y 5 mth», «12 kg»).



Below the section «Calculated dose», the grey bar shows the following data of the child: «Date of birth», «Weight», «Height», «BMI», Premature infant («PI») and chronological age («chronA»). For premature infants, instead of the chronological age, the gestational age at birth («GA») as well as the postmenstrual age («PMA») and the postnatal age («PNA») or the corrected age («corrA») are displayed. (For premature infants, see also chapter 3.3.)


Substance **Ibuprofen** 


Indication analgesia (mild / moderate pain), fever, perioperative analgesia 

Route of administration PO, liquid



Calculated dose  



General doses  


Substance **Ibuprofen** 

Indication analgesia (mild / moderate pain), fever, perioperative analgesia 

Route of administration PO, liquid

Calculated dose  

| Age       | Weight | PNA | Application | Type of dose | Dose             | Number of repetitions | Max single dose | Max daily dose | Remarks | GR  | Ref   |
|-----------|--------|-----|-------------|--------------|------------------|-----------------------|-----------------|----------------|---------|-----|---|
| 3 Y 5 mth | 12 kg  |     | PO          |              | 84 - 120 mg/dose | 3 x daily             |                 | 360 mg/day     |         | (A) |  |
| 3 Y 5 mth | 12 kg  |     | PO          |              | 60 - 84 mg/dose  | 4 x daily             |                 | 360 mg/day     |         | (A) |  |

 Date of birth 05.07.2019 Weight 12 kg Height 92 cm BMI 14 PI Yes GA 30 6/7 WOP **chronA** 3 Y 5 mth

### 7.2.1.6 Products in Switzerland

For users in Switzerland, clicking on «Products in Switzerland» will open a window below the windows «General doses» / «Substance specific remarks» with products containing the searched substance and route of administration and the galenic form (Ibuprofen, analgesia, oral, liquid in the example below).

General doses ▾
♥

**Substance specific remarks**

|                          |  |
|--------------------------|--|
| <b>attention</b>         | A good hydration of the patient is important. [152 (Algifor, 11/2019), 185]  |
| <b>Qo-value</b>          | 1 [58 (04/2019)]   |
| <b>contraindications</b> | infants <3 mth and <5 kg (indication fever, analgesia) [185]; dehydration, active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, HI or RI, hereditary fructose intolerance (sorbitol), patients under anticoagulatory therapy with acetylsalicylic acid [7, 152 (Algifor, 04/2019)] |
| <b>interactions</b>      | other NSAID, glucocorticoids, oral anticoagulants, digoxin, phenytoin, methotrexate, baclofen, quinolones, low-dose acetylsalicylic acid (can be substituted by diclofenac) [7, 122, 152 (Algifor, 04/2019)]   |

**11** Products in Switzerland ▾

|  |           |                   |
|--|-----------|-------------------|
| ALGIFOR Dolo forte Susp 200 mg/5ml         | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo forte Susp 400 mg/10ml        | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior 150 mg/7.5ml           | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior Susp 100 mg/5ml        | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Junior 100 mg/5ml mit Dosierspr    | ibuprofen | <a href="#">↗</a> |
| IRFEN DOLO Junior Susp 100 mg/5ml          | ibuprofen | <a href="#">↗</a> |
| IRFEN Junior Susp 100 mg/5ml               | ibuprofen | <a href="#">↗</a> |
| NUROFEN Dolo Junior Susp 100 mg/5ml Orange | ibuprofen | <a href="#">↗</a> |
| NUROFEN Junior forte Susp 200 mg/5ml Erdb  | ibuprofen | <a href="#">↗</a> |
| OPTIFEN Dolo Junior Susp 100 mg/5ml        | ibuprofen | <a href="#">↗</a> |
| OPTIFEN Junior Susp 100 mg/5ml             | ibuprofen | <a href="#">↗</a> |

By clicking on the symbol on the right in the field «Products in Switzerland» the short information of HCI Solutions AG is opened in [www.compendium.ch](http://www.compendium.ch) for the selected product, see below. To use the link from [www.compendium.ch](http://www.compendium.ch) back to PEdeDose, the user must be logged in to [www.compendium.ch](http://www.compendium.ch).

| 11 Products in Switzerland ▾               |           |                   |
|--|-----------|-------------------|
| ALGIFOR Dolo forte Susp 200 mg/5ml         | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo forte Susp 400 mg/10ml        | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior 150 mg/7.5ml           | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior Susp 100 mg/5ml        | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Junior 100 mg/5ml mit Dosierspr    | ibuprofen | <a href="#">↗</a> |
| IRFEN DOLO Junior Susp 100 mg/5ml          | ibuprofen | <a href="#">↗</a> |
| IRFEN Junior Susp 100 mg/5ml               | ibuprofen | <a href="#">↗</a> |
| NUROFEN Dolo Junior Susp 100 mg/5ml Orange | ibuprofen | <a href="#">↗</a> |
| NUROFEN Junior forte Susp 200 mg/5ml Erdb  | ibuprofen | <a href="#">↗</a> |
| OPTIFEN Dolo Junior Susp 100 mg/5ml        | ibuprofen | <a href="#">↗</a> |
| OPTIFEN Junior Susp 100 mg/5ml             | ibuprofen | <a href="#">↗</a> |

Below the window «Substance specific remarks» you will find a list of linked products in Switzerland that fit all or certain dosage datasets (three products in the example below, click to select the list), while below the window «Calculated dose» you will see only those products that fit the data set used for the calculation (two products in the example below, click «Products in Switzerland matching the data set of the calculated dose» to display the list for selection).

**Substance** Acetaminophen (Paracetamol) [Q](#)  
**Indication** analgesia (mild pain, pain score ≤3), fever [Q](#)  
**Route of administration** PO, liquid

**Calculated dose** ▾ [📄](#)

| Age | Weight | PNA | Application | Type of dose | Dose            | Number of repetitions | Max single dose | Max daily dose | Remarks | GR | Ref               |
|-----|--------|-----|-------------|--------------|-----------------|-----------------------|-----------------|----------------|---------|----|-------------------|
| 6 D | 3.5 kg | 6 D | PO          |              | 35 - 53 mg/dose | 3 - 4 x daily         |                 | 210 mg/day     |         | D  | <a href="#">📄</a> |

📄 **Date of birth** 30.11.2022 **Weight** 3.5 kg **Height** 50 cm **BMI** 14 **PI No** **chronA** 6 D

**2 Products in Switzerland matching the data set of the calculated dose** ▾

**General doses** ▾ [📄](#)

**Substance specific remarks**

**Qo-value** >0.9 [58 (03/2020)]

**liver insufficiency** adjust dose [152 (Dafalgan, 03/2020)]

**contraindications** severe liver dysfunction (cirrhosis and ascites)/acute hepatitis or decompensated active liver disease, hereditary constitutional hyperbilirubinemia (Meulengracht's syndrome) [152 (Dafalgan, 03/2020)]

**interactions** among others with enzyme inducers such as phenobarbital, carbamazepine, isoniazid, rifampicin, phenytoin (reduce max dosage of paracetamol to 75%, switch to alternative analgesic for long-term therapy) and with ethanol: increase in hepatotoxicity of paracetamol [85 (03/2020), 152 (Dafalgan, 03/2020)]

**3 Products in Switzerland** ▾

### 7.2.1.7 Product-specific remarks

By clicking on a product below the «Products in Switzerland» field («ALGIFOR Junior 100 mg/5ml» in the example), the «Product-specific remarks» window opens, as shown below. However, this information is available only in German and French for users in Switzerland.

**11** Products in Switzerland ▾

|  |           |                   |
|--|-----------|-------------------|
| ALGIFOR Dolo forte Susp 200 mg/5ml         | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo forte Susp 400 mg/10ml        | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior 150 mg/7.5ml           | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior Susp 100 mg/5ml        | ibuprofen | <a href="#">↗</a> |
| ALGIFOR Junior 100 mg/5ml mit Dosierspr    | ibuprofen | <a href="#">↗</a> |
| IRFEN DOLO Junior Susp 100 mg/5ml          | ibuprofen | <a href="#">↗</a> |
| IRFEN Junior Susp 100 mg/5ml               | ibuprofen | <a href="#">↗</a> |
| NUROFEN Dolo Junior Susp 100 mg/5ml Orange | ibuprofen | <a href="#">↗</a> |
| NUROFEN Junior forte Susp 200 mg/5ml Erdb  | ibuprofen | <a href="#">↗</a> |
| OPTIFEN Dolo Junior Susp 100 mg/5ml        | ibuprofen | <a href="#">↗</a> |
| OPTIFEN Junior Susp 100 mg/5ml             | ibuprofen | <a href="#">↗</a> |

**Produkt** ALGIFOR Junior 100 mg/5ml mit Dosierspr [🔍](#)

**Wirkstoff** ibuprofen [🔍](#)

**1** Indikation ▾

Analgesie (leichte / mittelstarke Schmerzen), Fieber, perioperative Analgesie

**Produkt spezifische Bemerkungen**

**Konzentration / Gehalt** 100 mg/5 mL = 20 mg/mL; 1 Flasche = 200 mL

**Eigenschaften Produkt** Konservierungsmittel / Hilfsstoffe: Saccharose (2.5 g/5 mL), Sorbitol, Xanthan, Ethanol (16.8 mg/5 mL), Natriumcyclamat, Polysorbat 80, Citronensäure-1-Wasser, Orangen Aroma, Natriumedetat, Natriumbenzoat (E211), gereinigtes Wasser (pro 5 mL <1 mmol Natrium) [152 (05/2022)]  
Geschmack: Orange [152 (05/2022)]

**Applikation** Handling: vor Gebrauch gut schütteln [152 (05/2022)]  
Dosierhilfe: Dosierspritze [152 (05/2022)]

**Haltbarkeit** Haltbarkeit nach Anbruch: 6 Mt bei RT [6 (03/2022)]

**Teilbarkeit / Sonde** Sonde: Verabreichung über Magen-, Duodenal- und Jejunalsonde möglich (kein spezifisches Absorptionsfenster bekannt, Resorption grösstenteils im Dünndarm) [7, 152 (05/2022), 158]

**Zulassung bei Kindern** ≥6 Mt und ≥5 kg [152 (03/2022)]

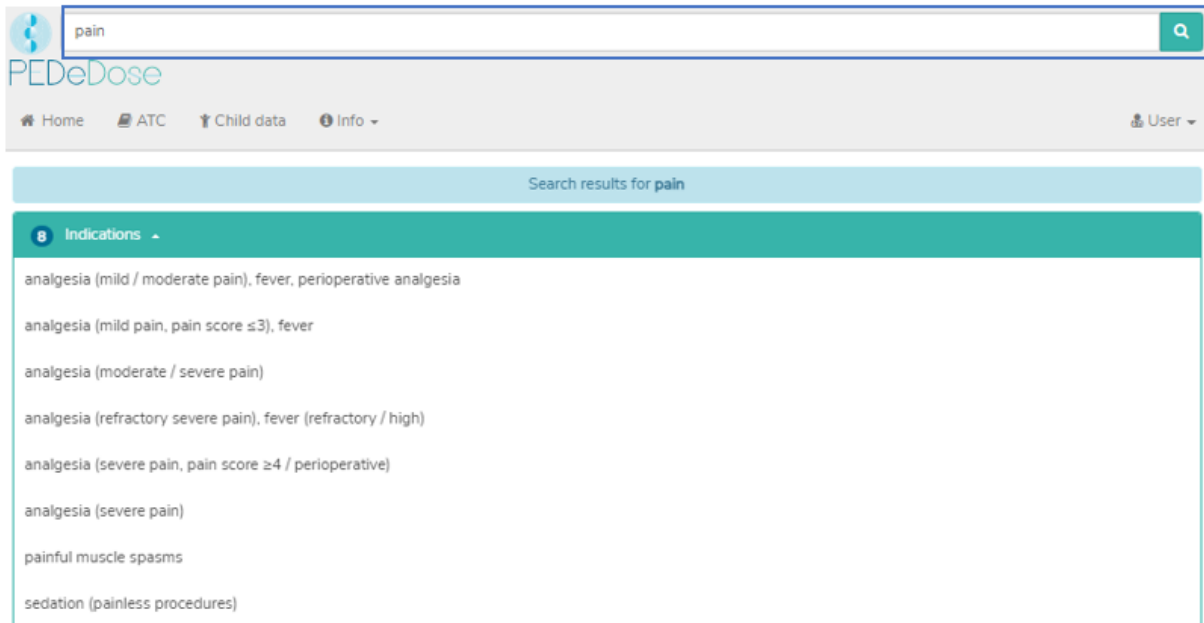
**Lagerbedingungen** bei RT lagern [152 (05/2022)]

In the «Product-specific remarks» window you can find information about the selected product, for instance «concentration/content», «preservatives/excipients», «dosing aids», «divisibility/enteral feeding tube», «storage conditions». «Product-specific remarks» of a product can be either «on label» or «off label». When assessing whether it is an «on label» or an «off label use», users must consult the product information. There aren't «Product-specific remarks» for all products.

## 7.2.2 Indication search

### 7.2.2.1 Indication

The indication is entered in the «Search» field (e.g. «pain»).



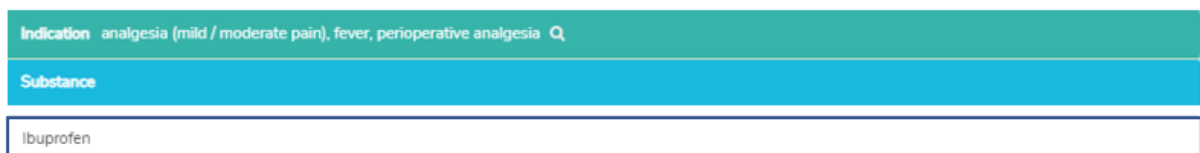
The screenshot shows the PEDeDose web application interface. At the top, there is a search bar with the text "pain" and a magnifying glass icon. Below the search bar, the PEDeDose logo and navigation menu (Home, ATC, Child data, Info) are visible. The main content area displays "Search results for pain" and a list of eight indications under the heading "Indications".

| Indications  |
|--|
| analgesia (mild / moderate pain), fever, perioperative analgesia |
| analgesia (mild pain, pain score $\leq 3$ ), fever               |
| analgesia (moderate / severe pain)                               |
| analgesia (refractory severe pain), fever (refractory / high)    |
| analgesia (severe pain, pain score $\geq 4$ / perioperative)     |
| analgesia (severe pain)  |
| painful muscle spasms  |
| sedation (painless procedures)                                   |

The results are listed below the field «Indications» (eight results for the example «pain»).

### 7.2.2.2 Substance

By clicking on an indication (i.e. «analgesia (mild / moderate pain), fever, perioperative analgesia»), the «Substance» field is opened (one substance for the selected indication):



The screenshot shows a close-up of the PEDeDose interface. The top bar displays the selected indication: "Indication analgesia (mild / moderate pain), fever, perioperative analgesia". Below this, the "Substance" field is highlighted in blue and contains the text "Ibuprofen".

PEDeDose is not intended to be used as a diagnosis handbook. Therefore, searching by an indication does not mean to get back a complete list of substances, which can be administered to a child with a specific diagnosis, but just a selection of substances. Vice versa not all of these substances should be prescribed for a child in a specific clinical situation.

### 7.2.2.3 Application

Clicking on a substance (example «Ibuprofen») opens the selection of the application (routes of administration/galenic groups) see below.

| Indication                        | analgesia (mild / moderate pain), fever, perioperative analgesia |
|-----------------------------------|--|
| Substance                         | Ibuprofen  |
| PO, liquid                        |  |
| PO, effervescent and liquid forms |  |
| PO, tablets, dragees, capsules    |  |
| REC                               |  |

### 7.2.2.4 General doses

Clicking on an application (example «PO, liquid») opens the «General doses» window, see below.

| Indication                    | analgesia (mild / moderate pain), fever, perioperative analgesia   |     |             |              |                   |                       |                 |                |         |     |     |
|-------------------------------|--|-----|-------------|--------------|-------------------|-----------------------|-----------------|----------------|---------|-----|-----|
| Substance                     | Ibuprofen  |     |             |              |                   |                       |                 |                |         |     |     |
| Route of administration       | PO, liquid   |     |             |              |                   |                       |                 |                |         |     |     |
| Calculated dose               |  |     |             |              |                   |                       |                 |                |         |     |     |
| General doses                 |  |     |             |              |                   |                       |                 |                |         |     |     |
| Age/PMA                       | Weight   | PNA | Application | Type of dose | Dose              | Number of repetitions | Max single dose | Max daily dose | Remarks | GR  | Ref |
| 3 mth - 6 mth and $\geq 5$ kg |  |     | PO          |              | 7 - 10 mg/kg/dose | 3 x daily             |                 | 30 mg/kg/day   |         | B   |     |
| 3 mth - 6 mth and $\geq 5$ kg |  |     | PO          |              | 5 - 7 mg/kg/dose  | 4 x daily             |                 | 30 mg/kg/day   |         | B   |     |
| 6 mth - 18 Y and 5 - 40 kg    |  |     | PO          |              | 7 - 10 mg/kg/dose | 3 x daily             |                 | 30 mg/kg/day   |         | (A) |     |
| 6 mth - 18 Y and 5 - 40 kg    |  |     | PO          |              | 5 - 7 mg/kg/dose  | 4 x daily             |                 | 30 mg/kg/day   |         | (A) |     |
| <18 Y and 40 - 50 kg          |  |     | PO          |              | 200 - 400 mg/dose | 3 - 4 x daily         |                 |                |         | (A) |     |
| $\geq 18$ Y or $\geq 50$ kg   |  |     | PO          |              | 400 - 600 mg/dose | 3 - 4 x daily         |                 | 2400 mg/day    |         | A   |     |
| Substance specific remarks    |  |     |             |              |                   |                       |                 |                |         |     |     |
| attention                     | A good hydration of the patient is important. [152 (Algifor, 11/2019), 185]  |     |             |              |                   |                       |                 |                |         |     |     |
| Q <sub>s</sub> -value         | 1 [58 (04/2019)]   |     |             |              |                   |                       |                 |                |         |     |     |
| contraindications             | infants <3 mth and <5 kg (indication fever, analgesia) [185]; dehydration, active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, HI or RI, hereditary fructose intolerance (sorbitol), patients under anticoagulatory therapy with acetylsalicylic acid [7, 152 (Algifor, 04/2019)] |     |             |              |                   |                       |                 |                |         |     |     |
| interactions                  | other NSAID, glucocorticoids, oral anticoagulants, digoxin, phenytoin, methotrexate, baclofen, quinolones, low-dose acetylsalicylic acid (can be substituted by diclofenac) [7, 122, 152 (Algifor, 04/2019)]   |     |             |              |                   |                       |                 |                |         |     |     |
| 11 Products in Switzerland    |  |     |             |              |                   |                       |                 |                |         |     |     |

In the «General doses» window you see the information described in chapter 7.2.1.4.



### 7.2.2.5 Calculated dose

A click on «Calculated dose» opens a window with the individually calculated dosage for the child whose data have been entered in the field «Child data». (Two dosage datasets are displayed in the example below because there are two different numbers of repetitions (3 x daily and 4 x daily).)

The dataset of the individually calculated dose shows the age and weight of the child for whom the dose has been calculated (in the example below «3 Y 5 mth», «12 kg»).

Below the section «Calculated dose», the grey bar shows the following data of the child: «Date of birth», «Weight», «Height», «BMI», premature infant («PI») and chronological age («chronA»). For premature infants, instead of the chronological age, the gestational age at birth («GA») as well as the postmenstrual age («PMA») and the postnatal age («PNA») or the corrected age («corrA») are displayed. (For preterm infants, see also chapter 3.3.)

Indication analgesia (mild / moderate pain), fever, perioperative analgesia Q

Substance Ibuprofen Q

Route of administration PO, liquid

Calculated dose 📄

General doses ❤️

Indication analgesia (mild / moderate pain), fever, perioperative analgesia Q

Substance Ibuprofen Q

Route of administration PO, liquid

Calculated dose 📄

| Age       | Weight | PNA | Application | Type of dose | Dose             | Number of repetitions | Max single dose | Max daily dose | Remarks | GR  | Ref |
|-----------|--------|-----|-------------|--------------|------------------|-----------------------|-----------------|----------------|---------|-----|-----|
| 3 Y 5 mth | 12 kg  |     | PO          |              | 84 - 120 mg/dose | 3 x daily             |                 | 360 mg/day     |         | (A) | 📄   |
| 3 Y 5 mth | 12 kg  |     | PO          |              | 60 - 84 mg/dose  | 4 x daily             |                 | 360 mg/day     |         | (A) | 📄   |

†
Date of birth 05.07.2019
 Weight 12 kg
 Height 92 cm
 BMI 14
 PI Yes
 GA 30 6/7 WOP
 chronA 3 Y 5 mth

### 7.2.2.6 Products in Switzerland

For users in Switzerland, clicking on «Products in Switzerland» will open a window below the windows «General doses» / «Substance specific remarks» with products containing the searched substance and route of administration and the galenic form (Ibuprofen, oral, liquid in the example stated below).


| General doses ▾            |  |
|----------------------------|--|
| Substance specific remarks |  |
| <b>attention</b>           | A good hydration of the patient is important. [152 (Algifor, 11/2019), 185]  |
| <b>Qe-value</b>            | 1 [58 (04/2019)]   |
| <b>contraindications</b>   | infants <3 mth and <5 kg (indication fever, analgesia) [185]; dehydration, active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, HI or RI, hereditary fructose intolerance (sorbitol), patients under anticoagulatory therapy with acetylsalicylic acid [7, 152 (Algifor, 04/2019)] |
| <b>interactions</b>        | other NSAID, glucocorticoids, oral anticoagulants, digoxin, phenytoin, methotrexate, baclofen, quinolones, low-dose acetylsalicylic acid (can be substituted by diclofenac) [7, 122, 152 (Algifor, 04/2019)]   |


| 11 Products in Switzerland ▾               |           |                   |
|--|-----------|-------------------|
| ALGIFOR Dolo forte Susp 200 mg/5ml         | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo forte Susp 400 mg/10ml        | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior 150 mg/7.5ml           | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Dolo Junior Susp 100 mg/5ml        | Ibuprofen | <a href="#">↗</a> |
| ALGIFOR Junior 100 mg/5ml mit Dosierspr    | Ibuprofen | <a href="#">↗</a> |
| IRFEN DOLO Junior Susp 100 mg/5ml          | Ibuprofen | <a href="#">↗</a> |
| IRFEN Junior Susp 100 mg/5ml               | Ibuprofen | <a href="#">↗</a> |
| NUROFEN Dolo Junior Susp 100 mg/5ml Orange | Ibuprofen | <a href="#">↗</a> |
| NUROFEN Junior forte Susp 200 mg/5ml Erdb  | Ibuprofen | <a href="#">↗</a> |
| OPTIFEN Dolo Junior Susp 100 mg/5ml        | Ibuprofen | <a href="#">↗</a> |
| OPTIFEN Junior Susp 100 mg/5ml             | Ibuprofen | <a href="#">↗</a> |

By clicking on the symbol on the right in the field «Products in Switzerland» the short information of HCI Solutions AG is opened in [www.compendium.ch](http://www.compendium.ch) for the selected product, see below. To use the link from [www.compendium.ch](http://www.compendium.ch) back to PEDeDose, the user must be logged in to [www.compendium.ch](http://www.compendium.ch).



| 11 Products in Switzerland ▾               |           |                   |
|--|-----------|-------------------|
| ALGIFOR Dolo forte Susp 200 mg/5ml         | Ibuprofen | <a href="#">🔗</a> |
| ALGIFOR Dolo forte Susp 400 mg/10ml        | Ibuprofen | <a href="#">🔗</a> |
| ALGIFOR Dolo Junior 150 mg/7.5ml           | Ibuprofen | <a href="#">🔗</a> |
| ALGIFOR Dolo Junior Susp 100 mg/5ml        | Ibuprofen | <a href="#">🔗</a> |
| ALGIFOR Junior 100 mg/5ml mit Dosierspr    | Ibuprofen | <a href="#">🔗</a> |
| IRFEN DOLO Junior Susp 100 mg/5ml          | Ibuprofen | <a href="#">🔗</a> |
| IRFEN Junior Susp 100 mg/5ml               | Ibuprofen | <a href="#">🔗</a> |
| NUROFEN Dolo Junior Susp 100 mg/5ml Orange | Ibuprofen | <a href="#">🔗</a> |
| NUROFEN Junior forte Susp 200 mg/5ml Erdb  | Ibuprofen | <a href="#">🔗</a> |
| OPTIFEN Dolo Junior Susp 100 mg/5ml        | Ibuprofen | <a href="#">🔗</a> |
| OPTIFEN Junior Susp 100 mg/5ml             | Ibuprofen | <a href="#">🔗</a> |



Below the window «Substance specific remarks» you will find a list of linked products in Switzerland that fit all or certain dosage datasets (eleven products in the example below, click to select the list), while below the window «Calculated dose» you will see only those products that fit the data set used for the calculation (seven products in the example below, click to select the list).


**Substance** Ibuprofen 


**Indication** analgesia (mild / moderate pain), fever, perioperative analgesia 



**Route of administration** PO, liquid

**Calculated dose**  

| Age   | Weight | PNA | Application | Type of dose | Dose            | Number of repetitions | Max single dose | Max daily dose | Remarks | GR | Ref   |
|-------|--------|-----|-------------|--------------|-----------------|-----------------------|-----------------|----------------|---------|----|---|
| 5 mth | 8 kg   |     | PO          |              | 56 - 80 mg/dose | 3 x daily             |                 | 240 mg/day     |         | B  |  |
| 5 mth | 8 kg   |     | PO          |              | 40 - 56 mg/dose | 4 x daily             |                 | 240 mg/day     |         | B  |  |

 **Date of birth** 05.07.2022 **Weight** 8 kg **Height** 60 cm **BMI** 22 **PI** No **chronA** 5 mth

**7** Products in Switzerland matching the data set of the calculated dose 

**General doses**  

**Substance specific remarks**

**attention** A good hydration of the patient is important. [152 (Algifor, 11/2019), 185]

**Q<sub>0</sub>-value** 1 [58 (04/2019)]

**contraindications** infants <3 mth and <5 kg (indication fever, analgesia) [185]; dehydration, active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, HI or RI, hereditary fructose intolerance (sorbitol), patients under anticoagulatory therapy with acetylsalicylic acid [7, 152 (Algifor, 04/2019)]

**interactions** other NSAID, glucocorticoids, oral anticoagulants, digoxin, phenytoin, methotrexate, baclofen, quinolones, low-dose acetylsalicylic acid (can be substituted by diclofenac) [7, 122, 152 (Algifor, 04/2019)]

**11** Products in Switzerland 

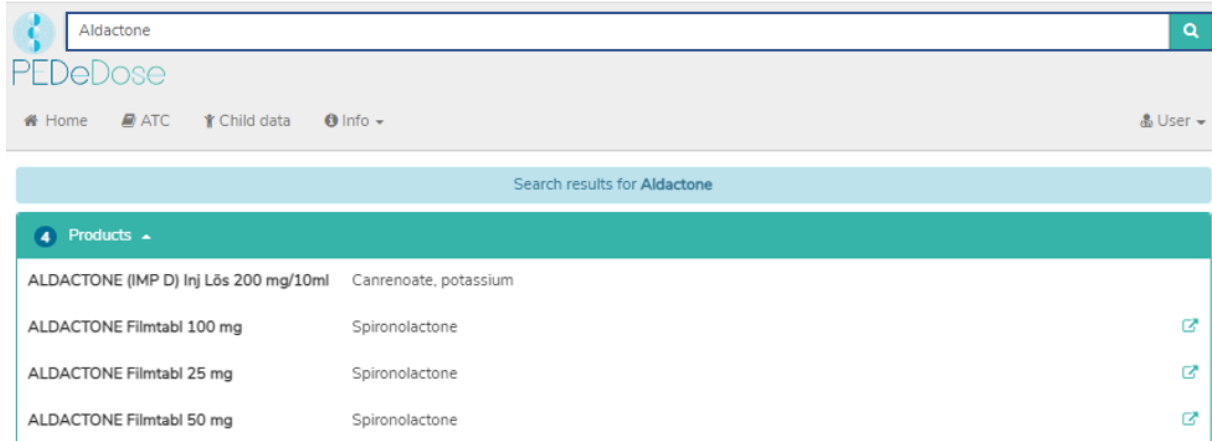
By clicking on the «Products in Switzerland» field and a product, the «Product-specific remarks» window opens, see chapter 7.2.1.7.

### 7.2.3 Product search

The product search is only available for users in Switzerland. Indications, dosages and «Product-specific remarks» displayed on a product can be either «on label» or «off label». When assessing whether it is an «on label use» or an «off label use», users must consult the product information.

### 7.2.3.1 Product

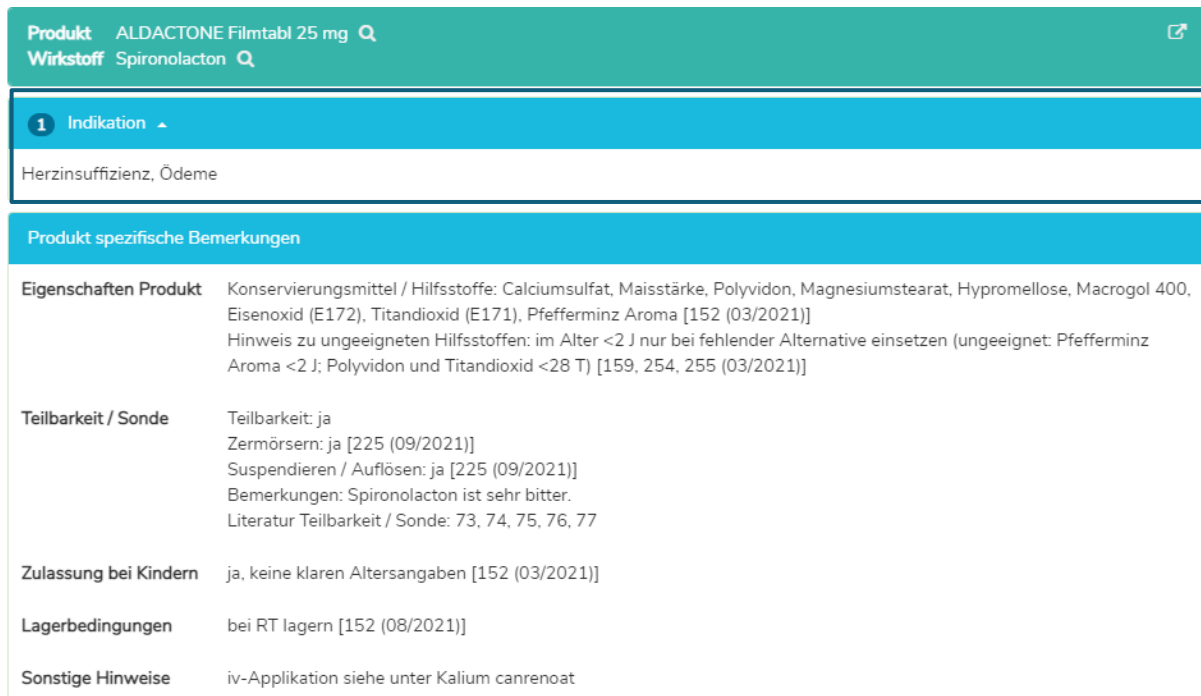
The product name is entered in the «Search» field (e.g. «Aldactone»).






The search results for «Aldactone» are listed below the heading «Products», see picture above (four products for Aldactone).


### 7.2.3.2 Indication

By clicking on a product in the list (e.g. «ALDACTONE Filmtabl 25 mg»), the selection of indications is opened (one indication for the example «ALDACTONE Filmtabl 25 mg»):



**Produkt** ALDACTONE Filmtabl 25 mg  

**Wirkstoff** Spironolacton 

**1 Indikation** 

Herzinsuffizienz, Ödeme

**Produkt spezifische Bemerkungen**

**Eigenschaften Produkt** Konservierungsmittel / Hilfsstoffe: Calciumsulfat, Maisstärke, Polyvidon, Magnesiumstearat, Hypromellose, Macrogol 400, Eisenoxid (E172), Titandioxid (E171), Pfefferminz Aroma [152 (03/2021)]  
Hinweis zu ungeeigneten Hilfsstoffen: im Alter <2 J nur bei fehlender Alternative einsetzen (ungeeignet: Pfefferminz Aroma <2 J; Polyvidon und Titandioxid <28 T) [159, 254, 255 (03/2021)]

**Teilbarkeit / Sonde** Teilbarkeit: ja  
Zermörsern: ja [225 (09/2021)]  
Suspendieren / Auflösen: ja [225 (09/2021)]  
Bemerkungen: Spironolacton ist sehr bitter.  
Literatur Teilbarkeit / Sonde: 73, 74, 75, 76, 77

**Zulassung bei Kindern** ja, keine klaren Altersangaben [152 (03/2021)]

**Lagerbedingungen** bei RT lagern [152 (08/2021)]











**Sonstige Hinweise** iv-Applikation siehe unter Kalium canrenoat

Only in the German and French PEDeDose version for users in Switzerland, you can find the «Product-specific remarks» regarding the selected product below the indications. In this field, additional

information about the selected product is displayed (e.g. «preservatives / excipients», «divisibility / enteral feeding tube», «storage conditions»). There aren't «Product-specific remarks» for all products.

### 7.2.3.3 General doses

Clicking an indication (in this case «heart failure, edema») opens the window «General doses», where all dosages for the selected product are displayed.

| Product ALDACTONE Filmtabl 25 mg  |        |     |             |              |                      |                       |  |                |  |    |   |
|--|--------|-----|-------------|--------------|----------------------|-----------------------|--|----------------|--|----|---|
| Substance Spironolactone          |        |     |             |              |                      |                       |  |                |  |    |   |
| Indication heart failure, edema   |        |     |             |              |                      |                       |  |                |  |    |   |
| Calculated dose                   |        |     |             |              |                      |                       |  |                |  |    |   |
| General doses                     |        |     |             |              |                      |                       |  |                |  |    |   |
| Age/PMA  | Weight | PNA | Application | Type of dose | Dose                 | Number of repetitions | Max single dose                                  | Max daily dose | Remarks                                    | GR | Ref   |
| <28 D  |        |     | PO          |              | 1 - 3 mg/kg/dose     | 1 x daily             |  |                | CI: RI                                     | D  |    |
| <28 D  |        |     | PO          |              | 0.5 - 1.5 mg/kg/dose | 2 x daily             |  |                | CI: RI                                     | D  |    |
| 28 D - 18 Y and <50 kg   |        |     | PO          |              | 1 - 2.5 mg/kg/dose   | 1 - 2 x daily         | higher doses may be necessary in resistant cases | 200 mg/day     |  | B  |  |
| ≥18 Y or ≥50 kg  |        |     | PO          | begin        | 100 mg/dose          | 1 x daily             |  | 200 mg/day     | daily dose can be split into several doses | A  |  |
| ≥18 Y or ≥50 kg  |        |     | PO          | maintenance  | 25 - 100 mg/dose     | 1 x daily             |  | 200 mg/day     | daily dose can be split into several doses | A  |  |

In the «General doses» window you see the information described in chapter 7.2.1.4.

### 7.2.3.4 Calculated dose

A click on «Calculated dose» opens a window with the individually calculated dose for the child whose data have been entered in the field «Child data» (see chapter 7.1).

**Product** ALDACTONE Filmtabl 25 mg  

**Substance** Spironolactone 

**Indication** heart failure, edema 

Calculated dose 

General doses 

**Product** ALDACTONE Filmtabl 25 mg  

**Substance** Spironolactone 

**Indication** heart failure, edema 

Calculated dose 

| Age   | Weight | PNA | Application | Type of dose | Dose            | Number of repetitions | Max single dose | Max daily dose | Remarks  | GR | Ref  |
|---|--------|-----|-------------|--------------|-----------------|-----------------------|-----------------|----------------|--|----|--|
| 3 Y 2 mth   | 12 kg  |     | PO          |              | 12 - 30 mg/dose | 1 - 2 x daily         |                 |                | higher doses may be necessary in resistant cases | B  |  |
| <p> <b>Date of birth</b> 06.10.2019 <b>Weight</b> 12 kg <b>Height</b> 92 cm <b>BMI</b> 14 <b>PI</b> No <b>chronA</b> 3 Y 2 mth</p> |        |     |             |              |                 |                       |                 |                |  |    |  |

The dataset of the individually calculated dose shows the age and weight of the child for whom the dose has been calculated (in the example above «3 Y 2 mth», «12 kg»).

Below the section «Calculated dose», the following child data are displayed in the grey bar: «Date of birth», «Weight», «Height», «BMI», preterm infant («PI») and chronological age («chronA»). For preterm infants instead of the chronological age the gestational age («GA») at birth and the post-menstrual age («PMA») as well as the post-natal age («PNA») or the corrected age («corrA») are displayed. (For premature infants, see also chapter 3.3.)

In the «Product-specific remarks» window you see the information described in chapter 7.2.1.7.

### 7.2.3.5 Dose conversion

The calculated dose can be converted by the calculator from the initial unit to an alternative unit (dispensing unit) (e.g. from mg to drops or mL). To do this, the field «Calculated dose in [alternative unit]» appears under the «Calculated dose» field, see below.

**Product** BECETAMOL Tropfen 100 mg/ml [Q](#)  
**Substance** Acetaminophen (Paracetamol) [Q](#)  
**Indication** analgesia (mild pain, pain score ≤3), fever [Q](#)

Calculated dose ▾ [📄](#)

Calculated dose in gtt ▾ [📄](#)

Calculated dose in mL ▾ [📄](#)

General doses ▲ [❤️](#)

By clicking on the field «Calculated dose» the dosage datasets for the individually calculated dose in drops (gtt) and in mL open in addition to the individually calculated dose, see below.

**Product** BECETAMOL Tropfen 100 mg/ml [Q](#)  
**Substance** Acetaminophen (Paracetamol) [Q](#)  
**Indication** analgesia (mild pain, pain score ≤3), fever [Q](#)

Calculated dose ▾ [📄](#)

| Age      | Weight        | PNA        | Application | Type of dose | Dose            | Number of repetitions | Max single dose | Max daily dose | Remarks | GR     | Ref               |
|----------|---------------|------------|-------------|--------------|-----------------|-----------------------|-----------------|----------------|---------|--------|-------------------|
| 7 wk     | 4.5 kg        |            | PO          |              | 68 - 90 mg/dose | 4 x daily             |                 |                |         | C      | <a href="#">📄</a> |
| <b>👤</b> | Date of birth | 18.10.2022 | Weight      | 4.5 kg       | Height          | 55 cm                 | BMI             | 15             | PI No   | chronA | 7 wk              |

Calculated dose in gtt ▾ [📄](#)

| Age      | Weight        | PNA        | Application | Type of dose | Dose             | Number of repetitions | Max single dose | Max daily dose | Remarks | GR     | Ref               |
|----------|---------------|------------|-------------|--------------|------------------|-----------------------|-----------------|----------------|---------|--------|-------------------|
| 7 wk     | 4.5 kg        |            | PO          |              | 14 - 18 gtt/dose | 4 x daily             |                 |                |         | C      | <a href="#">📄</a> |
| <b>👤</b> | Date of birth | 18.10.2022 | Weight      | 4.5 kg       | Height           | 55 cm                 | BMI             | 15             | PI No   | chronA | 7 wk              |

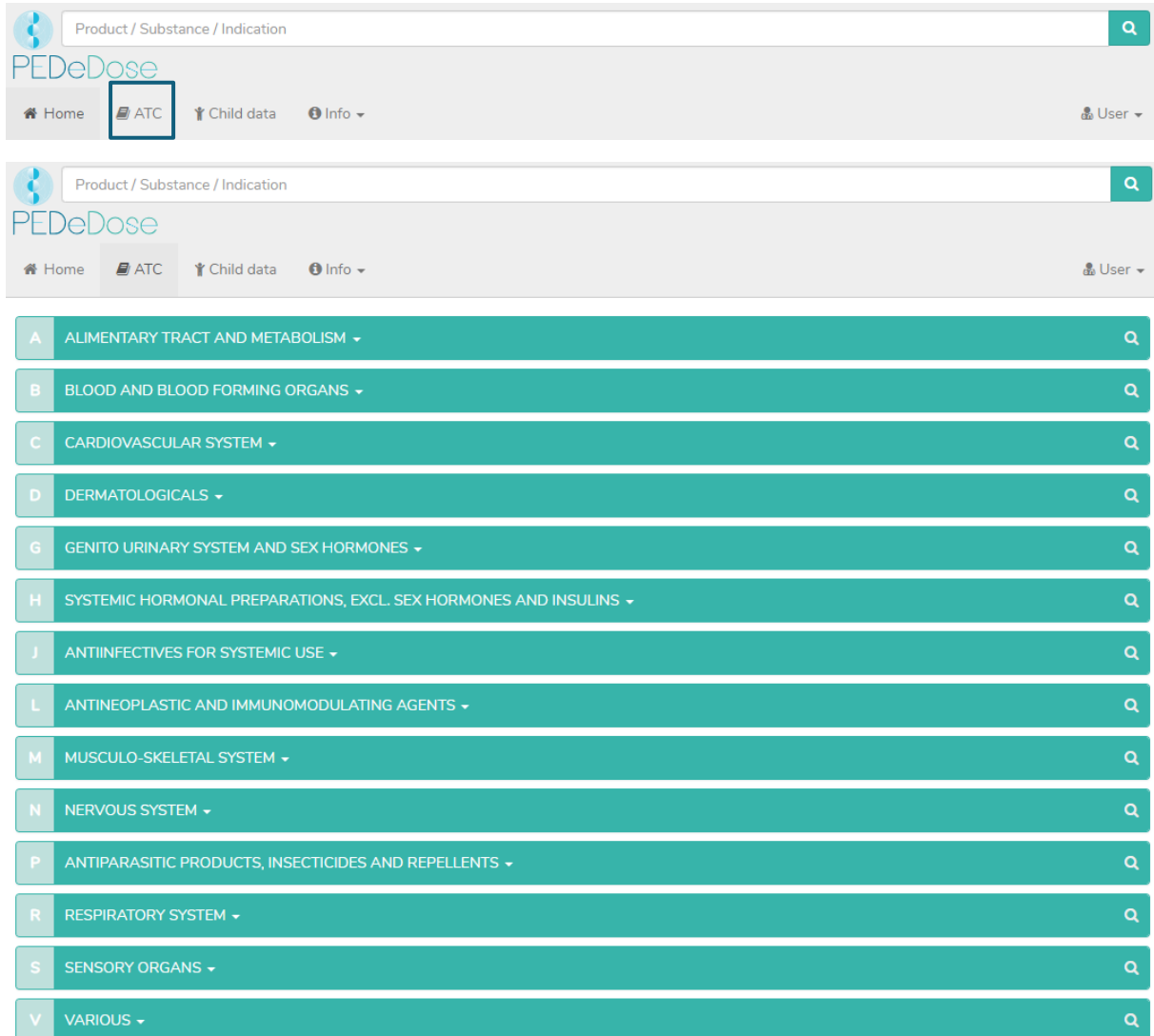
Calculated dose in mL ▾ [📄](#)

| Age      | Weight        | PNA        | Application | Type of dose | Dose                | Number of repetitions | Max single dose | Max daily dose | Remarks | GR     | Ref               |
|----------|---------------|------------|-------------|--------------|---------------------|-----------------------|-----------------|----------------|---------|--------|-------------------|
| 7 wk     | 4.5 kg        |            | PO          |              | 0.675 - 0.9 mL/dose | 4 x daily             |                 |                |         | C      | <a href="#">📄</a> |
| <b>👤</b> | Date of birth | 18.10.2022 | Weight      | 4.5 kg       | Height              | 55 cm                 | BMI             | 15             | PI No   | chronA | 7 wk              |



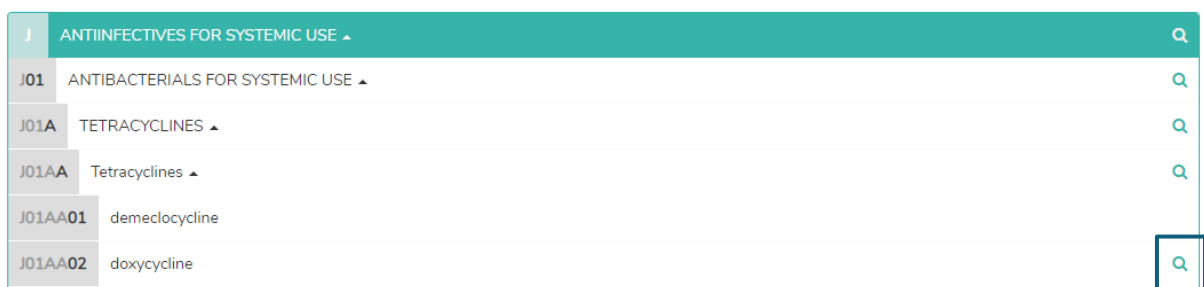
### 7.3 ATC code

By clicking the «ATC» button at the top of the page, the ATC code selection drops down, see below.



The screenshot shows the PEDeDose web application interface. At the top, there is a search bar labeled 'Product / Substance / Indication'. Below it, the PEDeDose logo and navigation menu are visible, including 'Home', 'ATC', 'Child data', and 'Info'. The 'ATC' button is highlighted with a red box. Below the navigation bar, a dropdown menu is open, displaying a list of ATC categories. Each category is represented by a teal bar with a white letter on the left and a magnifying glass icon on the right. The categories listed are: A ALIMENTARY TRACT AND METABOLISM, B BLOOD AND BLOOD FORMING ORGANS, C CARDIOVASCULAR SYSTEM, D DERMATOLOGICALS, G GENITO URINARY SYSTEM AND SEX HORMONES, H SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, J ANTIINFECTIVES FOR SYSTEMIC USE, L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, M MUSCULO-SKELETAL SYSTEM, N NERVOUS SYSTEM, P ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS, R RESPIRATORY SYSTEM, S SENSORY ORGANS, and V VARIOUS.

Select the appropriate path to go to the substance of interest. By clicking on the symbol on the right (magnifying glass), the substances (and if applicable, products) can be selected, see below.



The screenshot shows the expanded dropdown menu for the 'J ANTIINFECTIVES FOR SYSTEMIC USE' category. The menu is structured as follows:
 

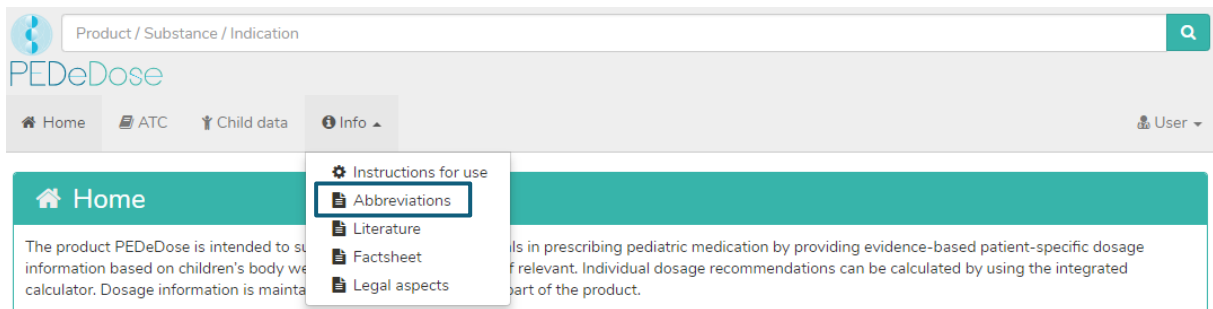
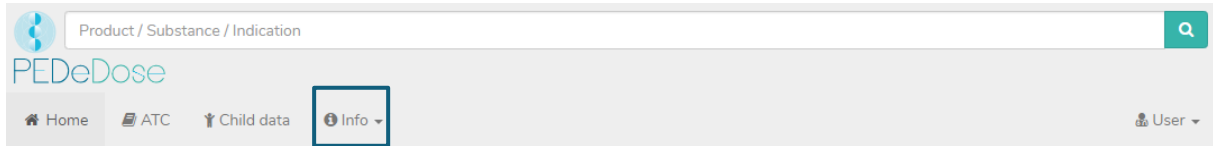
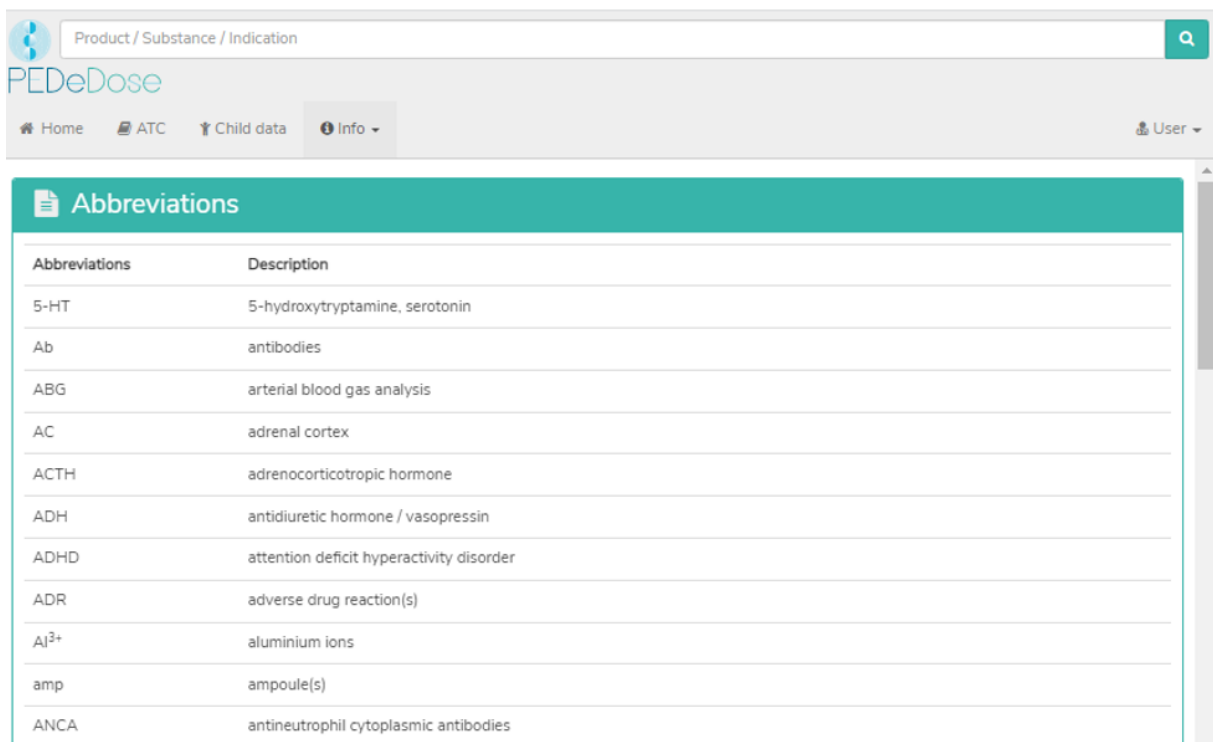
- J ANTIINFECTIVES FOR SYSTEMIC USE (with magnifying glass)
- J01 ANTIBACTERIALS FOR SYSTEMIC USE (with magnifying glass)
- J01A TETRACYCLINES (with magnifying glass)
- J01AA Tetracyclines (with magnifying glass)
- J01AA01 demeclocycline (with magnifying glass)
- J01AA02 doxycycline (with magnifying glass)

 A red box highlights the magnifying glass icon next to the 'J01AA02 doxycycline' entry.

The substances not marked with a magnifying glass are not included in PEDeDose.

## 7.4 Abbreviations

Click on the «Info» button at the top of the page to open a drop-down menu. Selecting «Abbreviations» opens the «Abbreviations» page, which lists all the abbreviations used in PEDeDose, see below.

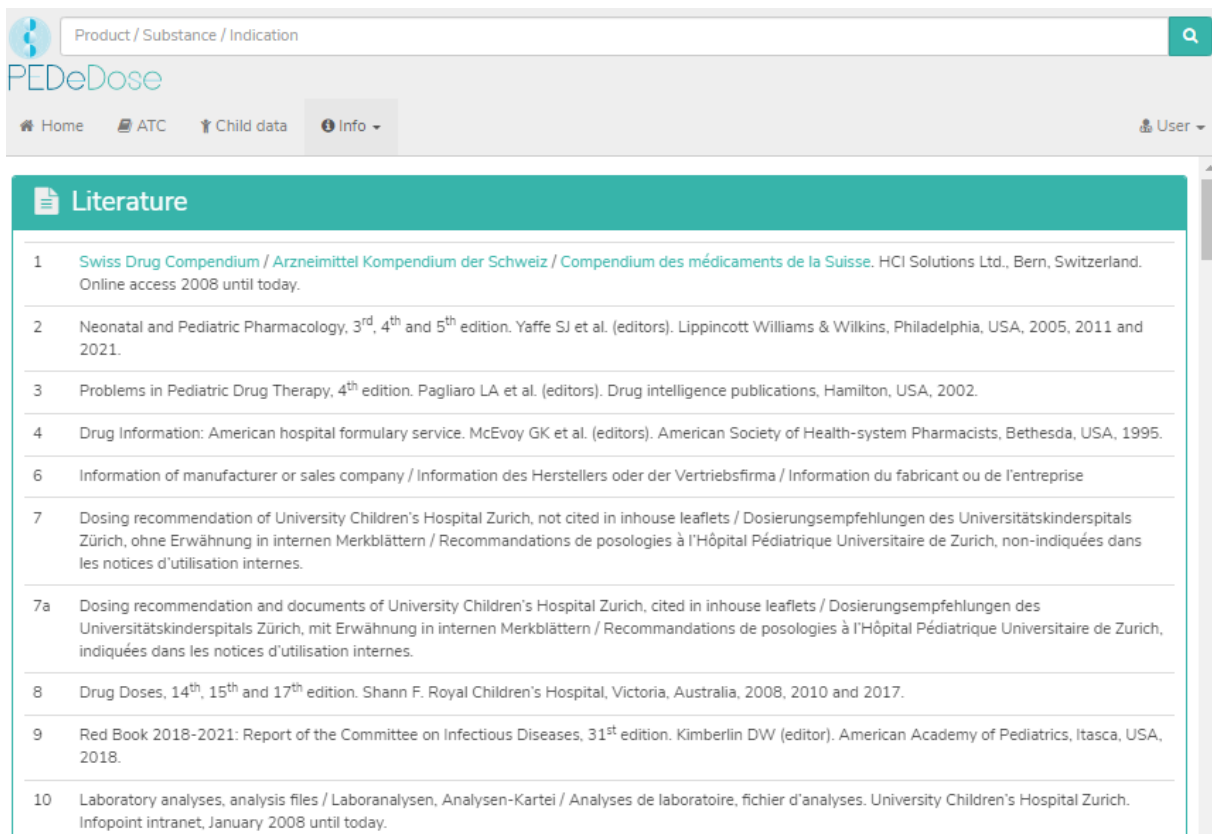
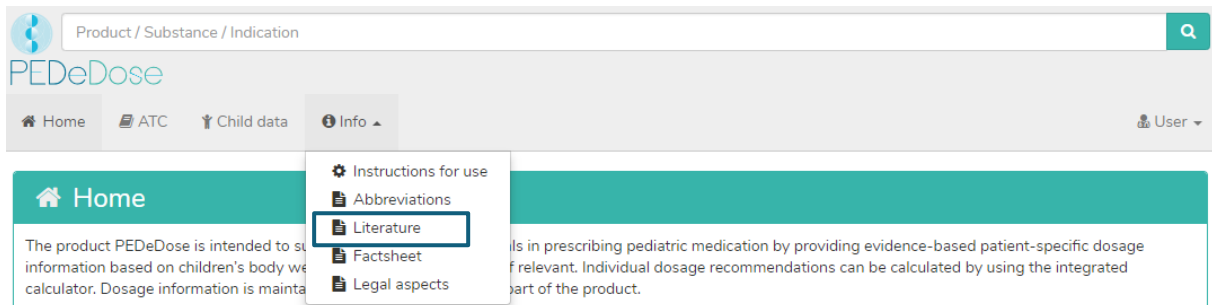
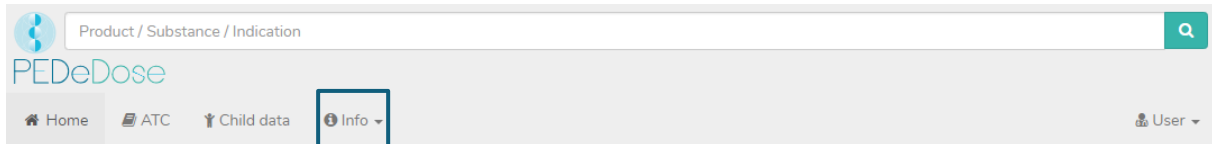
The screenshot displays the 'Abbreviations' page, which features a table listing various abbreviations and their corresponding descriptions. The table has two columns: 'Abbreviations' and 'Description'.

| Abbreviations    | Description                              |
|------------------|--|
| 5-HT             | 5-hydroxytryptamine, serotonin           |
| Ab               | antibodies                               |
| ABG              | arterial blood gas analysis              |
| AC               | adrenal cortex                           |
| ACTH             | adrenocorticotrophic hormone             |
| ADH              | antidiuretic hormone / vasopressin       |
| ADHD             | attention deficit hyperactivity disorder |
| ADR              | adverse drug reaction(s)                 |
| Al <sup>3+</sup> | aluminium ions                           |
| amp              | ampoule(s)                               |
| ANCA             | antineutrophil cytoplasmic antibodies    |

## 7.5 Literature

Click on the «Info» button at the top of the page to open a drop-down menu. Selecting «Literature» opens the «Literature» page, which lists all references used in PEDeDose.

The literature indicated in a dosage dataset refers to either the entire data set or only partial aspects of the data set.



## 8 Complaints and feedback

We kindly want to inform you that technical and content-related errors you have detected in PEdDose have to be reported immediately, but no later than 48 hours after detection to PEDEus via email ([info@pedeus.ch](mailto:info@pedeus.ch)). If an error occurs, PEdDose must no longer be used. Similarly, all serious incidents relating to the product must be reported to PEDEus and the competent authority of the member state where the user is based.

## 9 Contact information

### 9.1 General data

PEDEus AG  
Technoparkstrasse 1  
8005 Zurich  
Switzerland  
[info@pedeus.ch](mailto:info@pedeus.ch)  
+41 (0)44 521 73 80

### 9.2 Web addresses PEdDose application








- [www.pededose.ch](http://www.pededose.ch) (main address)
- [www.pededose.net](http://www.pededose.net)
- [www.pededose.org](http://www.pededose.org)

## 10 Primary label

Basis-UDI-DI of the PEDeDose Software: 7649996181015PEDeDoseSW

The UDI number for the current version of PEDeDose software can be found in the footer accessible to all registered users on the PEDeDose website.

The maximum product lifetime (version mentioned below) is 5 years.

|   |   |   |
|---|---|---|
|    | PEDeDose Software 2.4   |  |
|    | 2022-12   |   |
|    | 2027-12   |   |
|    | Available at:<br><a href="https://www.pededose.ch/">https://www.pededose.ch/</a>  |   |
| UDI-PI:   | Available at:<br><a href="https://www.pededose.ch/">https://www.pededose.ch/</a>  |   |
|   | PEDeus AG<br>Technoparkstrasse 1<br>8005 Zurich<br>Switzerland<br>info@pedeus.ch<br><a href="https://www.pedeus.ch/">https://www.pedeus.ch/</a> | CHRN:<br>CHE341324507<br><br>SRN:<br>CH-MF-000017885                              |
|  | European authorized<br>representative:<br>Johner Medical GmbH<br>Niddastrasse 91<br>60329 Frankfurt am Main<br>Germany                          | SRN:<br>DE-AR-000011832   |

## 11 Certifications

- PEDeus AG holds the ISO 13485:2016 certificate for «Design and Development, Production and Distribution of Pediatric Clinical Decision Support Software for Healthcare Professionals»
- PEDeus AG obtained the certification according to MDR, Class IIa Medical Device (PEDeDose Software) in December 2020.

## 12 Annexes

- Annex I Web service manual PEDeDose (for system integrators)
- Annex II Deep links advanced manual PEDeDose (for system integrators)