



# **Instructions for use**

# **PEDeDose**

**Pediatric Dosage Decision Support  
for Healthcare Professionals**

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## 1. General

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 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.

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 evidence-based and individualised 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" 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 adverse drug reactions 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.

### 1.1 Copyright

Copyright © 2018 PEDEus AG. All rights reserved.

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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 and 10 minutes every two months for system updates reserved). It can only be used by registered users. Access can be gained via direct registration at PEDeDose (via e-mail address) or in Switzerland via swiss-rx-login.

An access via IP address or a local installation may be used. 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 computers that use this IP address.

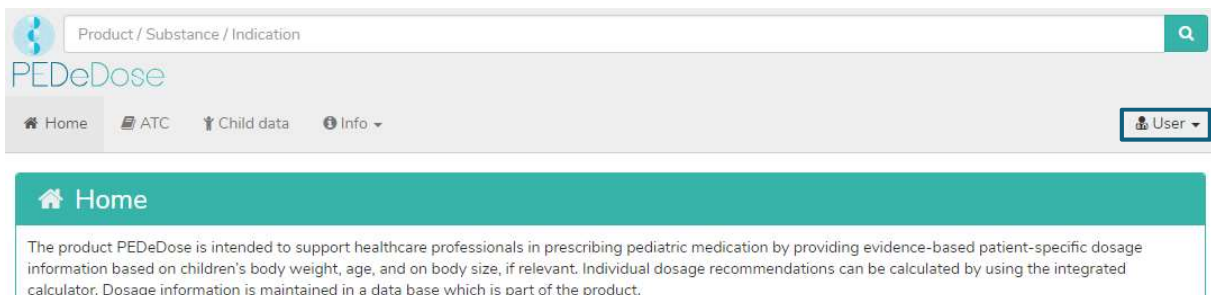
## 1.4 Language

PEDeDose is available in German, French and English.

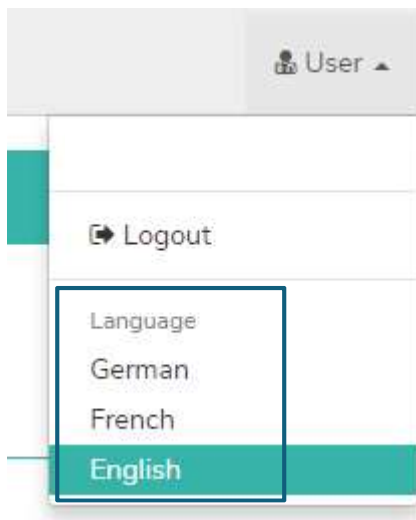
The language is selected on the top right of the home screen, see below:



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, Explorer, 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.

The local installation and the external website are distinguishable due to different URL addresses.

If local installation is chosen, the reliability of the user’s IT infrastructure must be permanently ensured, and the responsibilities/permissions of the local user are to be bilaterally defined.

Instructions for use version 06 applies for PEDeDose versions from 2.1.4 to 2.1.99 and replaces the previous version.

## 1.6 Residual risks

The following residual risks must be considered by the user:

- If a user enters incorrect data or (unintended) data is entered in PEdDose by another person without the user's knowledge, the received output might be incorrect.
- It might happen that PEdDose is temporarily unavailable or partially unavailable, or the update will be installed with some delay.
- 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.

## 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. For better assessment of the dosages' accuracy, grades of recommendation (A-D) are displayed right next to the dosages (see section 2.3).

However, those dosages do not consider individual characteristics such as any limited organ functions (kidney and liver insufficiency), drug interactions, obesity or genetic polymorphism.

### 2.1 Age and weight

Each dosage in PEDeDose is coupled to age and/or weight. 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 5 months and 30/31 days   |
| 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                  | From age 0 up to and including 27 days (up to 43 6/7 weeks of postmenstrual age (PMA) for preterm infants (PI)) |
| 32 W (PMA) – 36 W (PMA) | From week 32 and 0 days of postmenstrual age up to and including 35 weeks and 6 days of postmenstrual age       |
| ≤ 50 kg                 | Weight under or equal to 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 under 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 under 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 Maximum dosage

In the database, maximum individual and/or daily dosages are indicated to some extent. 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 applied.



## 2.3 Grade of recommendation

The grade of recommendation refers to the main dosage, not to maximum individual 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 trial (RCT); well-planned, single randomised controlled study; all-or-nothing principle, (approval by the Swiss authorities since 01/01/2011)             |
| (A)                     | Systematic review of randomised controlled trial (RCT); well-planned, single randomised controlled study; all-or-nothing principle, (approval by the Swiss authorities before 2011)                  |
| B                       | Systematic review of well-planned cohorts; well-planned single cohorts (and RCT with modest follow-up); outcome-research study; systematic review of case-control-studies; single case-control study |
| C                       | Case series; bad cohorts and case-control studies  |
| D                       | Expert's opinion without explicit clinical assessment; physiological models; comparisons; principles; "eminence-based-medicine"  |

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 section 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. At dosages that relate to the body surface of a child, the body surface is estimated based on the Mosteller formula. A few data sets do not permit dosage calculation. In this case, a corresponding message or a note is displayed.

### 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 (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 he needs 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.

### 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 of week 39 and 6 days is reached. They change into neonatal age for dosage calculation from gestational week 40 and 0 days. After that, the corrected age applies. The calculation according to corrected age is maintained until the end of the 36<sup>th</sup> month (chronological age), 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.

## 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. 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 application. PEDeDose is integrated via web service.

### 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<br>OR >125% (if no maximum dosage is available) | >300%        |
| Narrow therapeutic index | Below | 95 – 105%   | 90 – 95%        | < 90%  |              |
|                          | Above |             | 105 – 111%      | Maximum dosage<br>OR >111% (if no maximum dosage is available) | >150%        |

\* The status/colours and/or symbols are provided by the “clinical information system”; the last column (toxic/black) may be shown together with “Dangerous/red”.

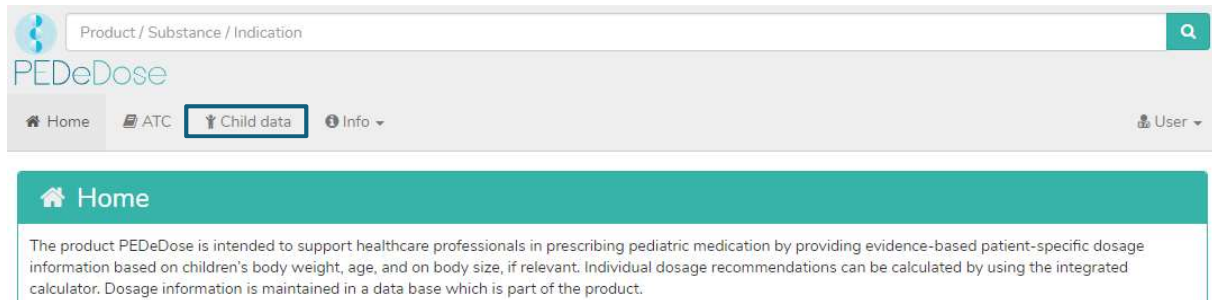
If PEDeDose is specified in ranges, the highest (for upper limits) or the lowest value (for lower limits) is used for the tolerance calculation.

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

## 5. Detailed instructions for use

### 5.1 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.



For individual dosage calculation, the following information is entered:

- 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” in preterm infant)



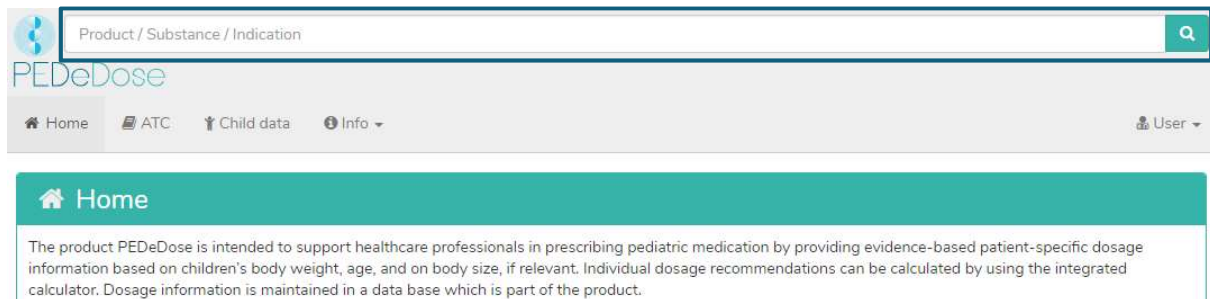
For preterm infants, select “Yes” in the field “Preterm infant”. Subsequently, the gestational age at birth is entered in weeks and days (see section 3.3).

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”).

The entered data is saved by clicking on the “Save” button or deleted by clicking on the “Delete” button.

## 5.2 Search

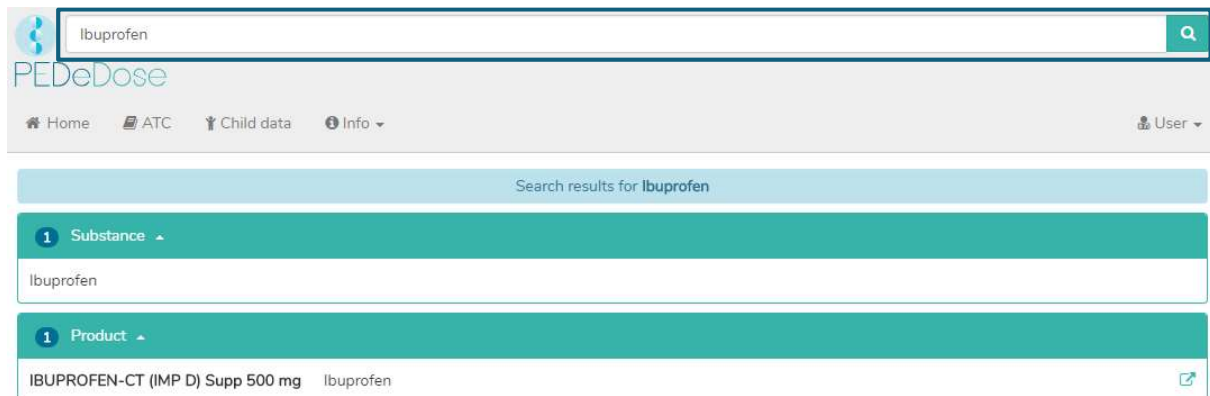
In the “Search” field, either a substance name, a drug indication or a product name can be entered; at least three letters or two letters (characters) and % can be entered. The search function is not case-sensitive.



### 5.2.1 Substance search

#### a) Substance

The substance name is entered in the “Search” field (e.g. Ibuprofen).



The search results are displayed below the “Search” field. For the example “Ibuprofen”, the search returned one substance and one product as a result.

### b) Indication

By clicking on the substance (Ibuprofen), the “Indication” field is opened (one indication for the selected example):

|            |   |
|------------|---|
| Substance  | Ibuprofen   |
| Indication | analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia |

### c) Application

Clicking on an indication (in this case “analgesia (mild and moderate pain), fever (2<sup>nd</sup> choice), perioperative analgesia”) opens the selection of application (route of administrations/galenic groups), see below.

|             |  |
|-------------|--|
| Substance   | Ibuprofen  |
| Indication  | analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia          |
| Application | PO, liquid<br>PO, effervescent and liquid forms<br>PO, tablets, dragees, capsules<br>REC |

### d) General Doses

Clicking on an application (i.e. “PO, liquid) opens the “General Doses” window, see below.

| Substance                  | Ibuprofen   |    |             |              |                   |                       |                     |                |         |     |     |
|----------------------------|---|----|-------------|--------------|-------------------|-----------------------|---------------------|----------------|---------|-----|-----|
| Indication                 | analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia |    |             |              |                   |                       |                     |                |         |     |     |
| Route of administration    | PO, liquid  |    |             |              |                   |                       |                     |                |         |     |     |
| Calculated dose            |   |    |             |              |                   |                       |                     |                |         |     |     |
| General doses              |   |    |             |              |                   |                       |                     |                |         |     |     |
| Age/PMA                    | Weight  | PI | Application | Type of dose | Dose              | Number of repetitions | Max individual dose | Max daily dose | Remarks | GR  | Ref |
| 6 mth - 12 Y and 5 - 40 kg |   |    | PO          |              | 7 - 10 mg/kg/dose | 3 x daily             |                     | 30 mg/kg/day   |         | (A) |     |
| 6 mth - 12 Y and 5 - 40 kg |   |    | PO          |              | 5 - 7 mg/kg/dose  | 4 x daily             |                     | 30 mg/kg/day   |         | (A) |     |
| ≥ 12 Y or ≥ 40 kg          |   |    | PO          |              | 200 - 400 mg/dose | 4 - 6 x daily         |                     | 2'400 mg/day   |         | (A) |     |
| 4 Products in Switzerland  |   |    |             |              |                   |                       |                     |                |         |     |     |

The “General Doses” window provides the following information:

| General doses Information | Explanation  |
|---------------------------|--|
| Age/PMA                   | Age of the child for whom the dosage is recommended<br><br>(PMA: postmenstrual age, in case of a dose for a preterm infant, displayed by “PI” between the headings “weight” and “application”)               |
| Weight                    | Weight of the child for whom the dosage is recommended   |
| PI                        | Preterm infant (a dosage line with “PI” is recommended for 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 individual 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 2.3)  |
| Ref                       | Reference (number of reference on which the dosage is based), see “Literature” (chapter 5.5) for reference list. The “book symbol” works as a “mouse-over button (does not work on tablets and smartphones). |

### e) 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”. Below the section “Calculated dose”, the child data (date of birth, weight, height, preterm infant, GA (gestational age) at birth) are displayed. (There are two rows in the example below because there are two different numbers of repetitions (3 x daily and 4 x daily).)

**Substance** ibuprofen  
**Indication** analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia  
**Route of administration** PO, liquid

Calculated dose ▾ 📅

General doses ▾ ❤️

4 Products in Switzerland ▾

**Substance** ibuprofen  
**Indication** analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia  
**Route of administration** PO, liquid

Calculated dose ▲ 📅

| Age                        | Weight     | PI     | Application | Type of dose | Dose             | Number of repetitions | Max individual dose | Max daily dose | Remarks | GR          | Ref        |
|----------------------------|------------|--------|-------------|--------------|------------------|-----------------------|---------------------|----------------|---------|-------------|------------|
| 6 mth - 12 Y and 5 - 40 kg |            |        | PO          |              | 84 - 120 mg/dose | 3 x daily             |                     | 360 mg/day     |         | (A)         | 📄          |
| 6 mth - 12 Y and 5 - 40 kg |            |        | PO          |              | 60 - 84 mg/dose  | 4 x daily             |                     | 360 mg/day     |         | (A)         | 📄          |
| 👤 Date of birth            | 10.05.2015 | Weight | 12 kg       | Height       | 92 cm            | BMI                   | 14                  | Preterm infant | Yes     | GA at birth | 30 6/7 WOP |

### f) Products in Switzerland

For Swiss users, clicking on “Products in Switzerland” will open a window with products containing the substance and route of administration of interest (Ibuprofen, oral, liquid in the example stated below).

**Substance** ibuprofen  
**Indication** analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia  
**Route of administration** PO, liquid

Calculated dose ▾ 📅







General doses ▾ ❤️

4 Products in Switzerland ▲

|                                     |           |   |
|-------------------------------------|-----------|---|
| ALGIFOR Dolo forte Susp 200 mg/5ml  | ibuprofen | 📄 |
| ALGIFOR Dolo Junior 150 mg/7.5ml    | ibuprofen | 📄 |
| ALGIFOR Dolo Junior Susp 100 mg/5ml | ibuprofen | 📄 |
| ALGIFOR Junior Susp 100 mg/5ml      | ibuprofen | 📄 |









By clicking on the button on the right in the field “Products in Switzerland” the short information of HCl Solutions AG is opened for the selected product, see below.

|   |   |
|---|---|
| <b>Substance</b>  | ibuprofen   |
| <b>Indication</b>   | analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia               |
| <b>Route of administration</b>  | PO, liquid  |
| Calculated dose ▾  |   |
| General doses ▾    |   |
| 4 Products in Switzerland ▾   |   |
| ALGIFOR Dolo forte Susp 200 mg/5ml  | ibuprofen  |
| ALGIFOR Dolo Junior 150 mg/7.5ml  | ibuprofen  |
| ALGIFOR Dolo Junior Susp 100 mg/5ml   | ibuprofen  |
| ALGIFOR Junior Susp 100 mg/5ml  | ibuprofen  |

### g) General remarks

By clicking on a product below the “Product in Switzerland” field (ALGIFOR Junior Susp 100 mg/5ml in the example), the “General remarks” window opens. However, this information is available only in German and French.

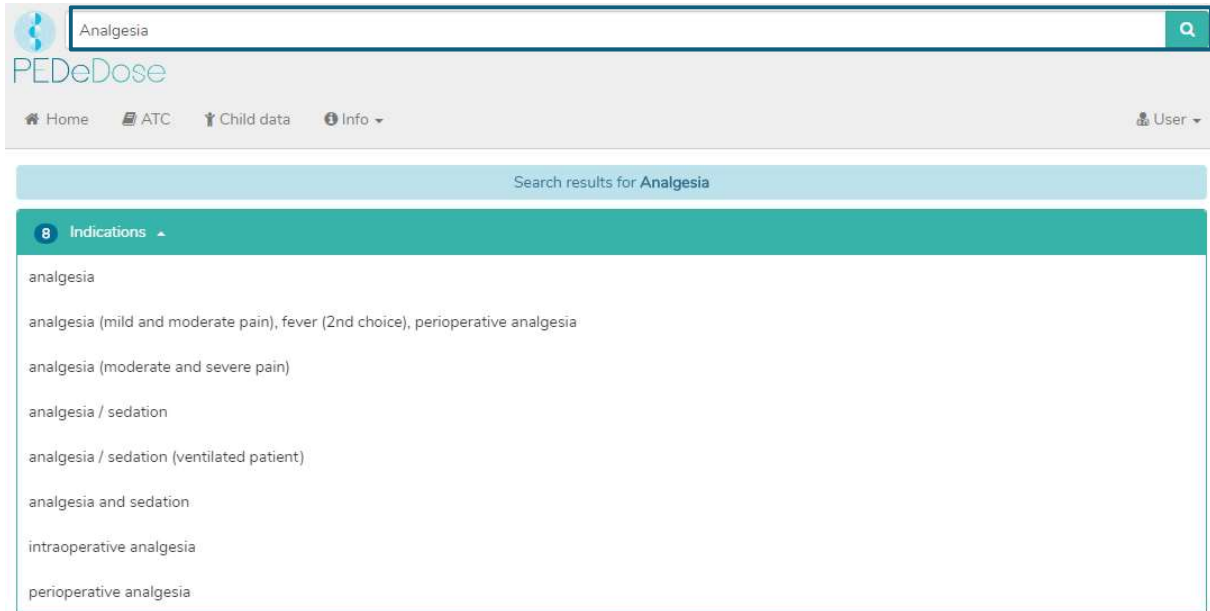
|   |   |
|---|---|
| <b>Substance</b>  | ibuprofen   |
| <b>Indication</b>   | analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia                 |
| <b>Route of administration</b>  | PO, liquid  |
| Calculated dose ▾  |   |
| General doses ▾    |   |
| 4 Products in Switzerland ▾   |   |
| ALGIFOR Dolo forte Susp 200 mg/5ml  | ibuprofen  |
| ALGIFOR Dolo Junior 150 mg/7.5ml  | ibuprofen  |
| ALGIFOR Dolo Junior Susp 100 mg/5ml   | ibuprofen  |
| ALGIFOR Junior Susp 100 mg/5ml  | ibuprofen  |

In the “General remarks” window you can find information about the selected product, for instance preservatives, contraindications, concentration, dosing aids. “General 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 are not “General remarks” for all products.

## 5.2.2 Indication search

### a) Indication

The indication is entered in the “Search” field (e.g. analgesia).



The screenshot shows the PEDeDose web application interface. At the top, there is a search bar containing the text 'Analgesia'. Below the search bar, the application header includes navigation links for Home, ATC, Child data, and Info, along with a user profile icon. The main content area displays 'Search results for Analgesia'. A dropdown menu titled '8 Indications' is open, listing the following search results:

- analgesia
- analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia
- analgesia (moderate and severe pain)
- analgesia / sedation
- analgesia / sedation (ventilated patient)
- analgesia and sedation
- intraoperative analgesia
- perioperative analgesia

The results are listed below the field “Indications” (8 results for the example analgesia).

### b) Substance

By clicking on an indication (i.e. analgesia (mild and moderate pain), fever (2<sup>nd</sup> choice), perioperative analgesia), the “Substance” field is opened (one substance for the selected indication):



The screenshot shows a close-up of the application interface. The 'Indication' field is highlighted in green and contains the text: 'analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia'. Below it, the 'Substance' field is highlighted in blue and contains the text: 'Ibuprofen'.

PEDeDose is not intended to be used as an indication handbook. Therefore, searching by an indication does not mean to get back a complete list of substances, which should be applied to a child with a specific diagnosis. Search by indication results in substances and products, which might be applied in a specific clinical situation.

### c) Application

Clicking on a substance (example “Ibuprofen”) opens the selection of the application (route of administrations/galenic groups) see below.

|   |
|---|
| <b>Substance</b> Ibuprofen  |
| <b>Indication</b>   |
| analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia |
| PO, liquid  |
| PO, effervescent and liquid forms   |
| PO, tablets, dragees, capsules  |
| REC   |

### d) General doses

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

| <b>Substance</b> Ibuprofen     |   |    |             |              |                   |                       |                     |                |         |     |     |
|--------------------------------|---|----|-------------|--------------|-------------------|-----------------------|---------------------|----------------|---------|-----|-----|
| <b>Indication</b>              | analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia |    |             |              |                   |                       |                     |                |         |     |     |
| <b>Route of administration</b> | PO, liquid  |    |             |              |                   |                       |                     |                |         |     |     |
| <b>Calculated dose</b> ▾       |   |    |             |              |                   |                       |                     |                |         |     |     |
| <b>General doses</b> ▾         |   |    |             |              |                   |                       |                     |                |         |     |     |
| Age/PMA                        | Weight  | PI | Application | Type of dose | Dose              | Number of repetitions | Max individual dose | Max daily dose | Remarks | GR  | Ref |
| 6 mth - 12 Y and 5 - 40 kg     |   |    | PO          |              | 7 - 10 mg/kg/dose | 3 x daily             |                     | 30 mg/kg/day   |         | (A) |     |
| 6 mth - 12 Y and 5 - 40 kg     |   |    | PO          |              | 5 - 7 mg/kg/dose  | 4 x daily             |                     | 30 mg/kg/day   |         | (A) |     |
| ≥ 12 Y or ≥ 40 kg              |   |    | PO          |              | 200 - 400 mg/dose | 4 - 6 x daily         |                     | 2'400 mg/day   |         | (A) |     |
| 4 Products in Switzerland ▾    |   |    |             |              |                   |                       |                     |                |         |     |     |

In the “General doses” window you see the information described in point d)5.2.1.

### e) 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”. Below the section “Calculated dose”, the child data (date of birth, weight, height, preterm infant, GA (gestational age) at birth) are shown. (Two lines are displayed in the example below because there are two different numbers of repetitions (3 x daily and 4 x daily).)



Substance: Ibuprofen  
Indication: analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia  
Route of administration: PO, liquid

Calculated dose ▾

General doses ▾

4 Products in Switzerland ▾

Substance: Ibuprofen  
Indication: analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia  
Route of administration: PO, liquid

Calculated dose ▾

| Age                        | Weight     | PI     | Application | Type of dose | Dose             | Number of repetitions | Max individual dose | Max daily dose | Remarks | GR          | Ref        |
|----------------------------|------------|--------|-------------|--------------|------------------|-----------------------|---------------------|----------------|---------|-------------|------------|
| 6 mth - 12 Y and 5 - 40 kg |            |        | PO          |              | 84 - 120 mg/dose | 3 x daily             |                     | 360 mg/day     |         | (A)         |            |
| 6 mth - 12 Y and 5 - 40 kg |            |        | PO          |              | 60 - 84 mg/dose  | 4 x daily             |                     | 360 mg/day     |         | (A)         |            |
| † Date of birth            | 10.05.2015 | Weight | 12 kg       | Height       | 92 cm            | BMI                   | 14                  | Preterm infant | Yes     | GA at birth | 30 6/7 WOP |

### f) Products in Switzerland

For Swiss users, clicking on “Products in Switzerland” opens a window with products with the searched substance and application (example Ibuprofen, PO, liquid), see below.

Substance: Ibuprofen  
Indication: analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia  
Route of administration: PO, liquid







Calculated dose ▾

General doses ▾

4 Products in Switzerland ▾

|                                     |           |  |
|-------------------------------------|-----------|--|
| ALGIFOR Dolo forte Susp 200 mg/5ml  | Ibuprofen |  |
| ALGIFOR Dolo Junior 150 mg/7.5ml    | Ibuprofen |  |
| ALGIFOR Dolo Junior Susp 100 mg/5ml | Ibuprofen |  |
| ALGIFOR Junior Susp 100 mg/5ml      | Ibuprofen |  |

By clicking on the button on the right in the field “Product in Switzerland” the short information of HCl Solutions AG is opened for the selected product, see below.

|   |   |
|---|---|
| <b>Substance</b>  | ibuprofen   |
| <b>Indication</b>   | analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia               |
| <b>Route of administration</b>  | PO, liquid  |
| Calculated dose ▾  |   |
| General doses ▾    |   |
| 4 Products in Switzerland ▾   |   |
| ALGIFOR Dolo forte Susp 200 mg/5ml  | ibuprofen  |
| ALGIFOR Dolo Junior 150 mg/7.5ml  | ibuprofen  |
| ALGIFOR Dolo Junior Susp 100 mg/5ml   | ibuprofen  |
| ALGIFOR Junior Susp 100 mg/5ml  | ibuprofen  |

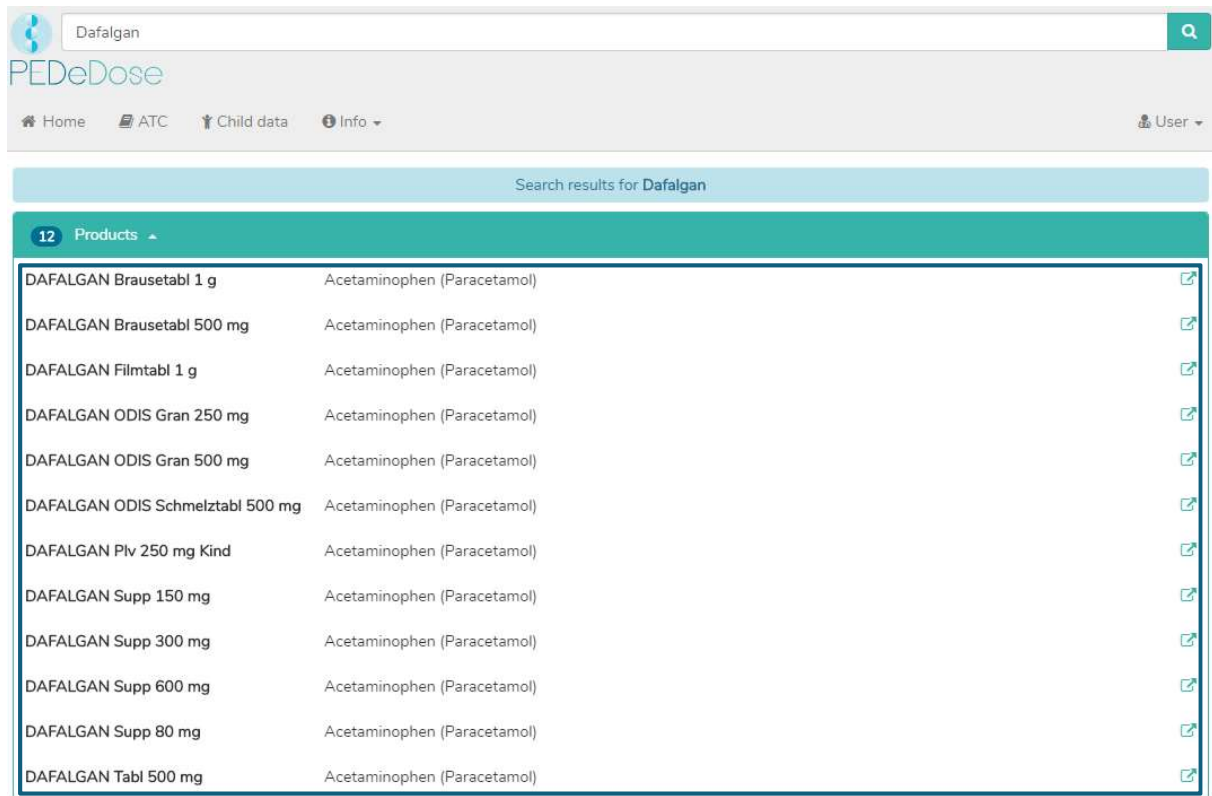
By clicking on the “Product in Switzerland” field (ALGIFOR Junior Susp 100 mg/5ml in the example), the “General remarks” window opens, see section g) 5.2.1.

### 5.2.3 Product search

The product search is only available for Swiss users. Indications, dosages and “General 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.

#### a) Product

The product name is entered in the “Search field” (e.g. Dafalgan).



| Search results for Dafalgan      |                             |
|----------------------------------|-----------------------------|
| 12 Products                      |                             |
| DAFALGAN Brausetabl 1 g          | Acetaminophen (Paracetamol) |
| DAFALGAN Brausetabl 500 mg       | Acetaminophen (Paracetamol) |
| DAFALGAN Filmtabl 1 g            | Acetaminophen (Paracetamol) |
| DAFALGAN ODIS Gran 250 mg        | Acetaminophen (Paracetamol) |
| DAFALGAN ODIS Gran 500 mg        | Acetaminophen (Paracetamol) |
| DAFALGAN ODIS Schmelztabl 500 mg | Acetaminophen (Paracetamol) |
| DAFALGAN Plv 250 mg Kind         | Acetaminophen (Paracetamol) |
| DAFALGAN Supp 150 mg             | Acetaminophen (Paracetamol) |
| DAFALGAN Supp 300 mg             | Acetaminophen (Paracetamol) |
| DAFALGAN Supp 600 mg             | Acetaminophen (Paracetamol) |
| DAFALGAN Supp 80 mg              | Acetaminophen (Paracetamol) |
| DAFALGAN Tabl 500 mg             | Acetaminophen (Paracetamol) |

The search results for Dafalgan are listed below the heading “Products”, see picture above (12 products for Dafalgan).

### b) Indication

By clicking on a product in the list (e.g. Dafalgan Supp 80 mg), the selection of indications is opened (two indications for Dafalgan Supp 80 mg example):



**Product** Dafalgan Supp 80 mg  
**Substance** Acetaminophen (Paracetamol)

**2 Indications**

- fever, mild pain (pain score ≤3), extended administration and outpatient sector
- severe pain and postoperative (pain score ≥4)

Only in the German and French PEDeDose version, you can find the “General remarks” regarding the selected product below the indications. In this field, additional information about the selected product is displayed (e.g. preservatives, excipients, contraindications). There are not “General remarks” for all products.

### c) General doses

Clicking an indication (in this case “fever, mild pain (pain score  $\leq 3$ ), extended administration and outpatient sector”) opens the window “General doses”, where all dosages for the selected product are displayed, see below.

| <b>Product</b>          | Dafalgan Supp 80 mg  |    |             |              |               |                       |                     |                |         |    |     |
|-------------------------|--|----|-------------|--------------|---------------|-----------------------|---------------------|----------------|---------|----|-----|
| <b>Substance</b>        | Acetaminophen (Paracetamol)  |    |             |              |               |                       |                     |                |         |    |     |
| <b>Indication</b>       | fever, mild pain (pain score $\leq 3$ ), extended administration and outpatient sector |    |             |              |               |                       |                     |                |         |    |     |
| Calculated dose ▾       |  |    |             |              |               |                       |                     |                |         |    |     |
| General doses ▲         |  |    |             |              |               |                       |                     |                |         |    |     |
| Age/PMA                 | Weight   | PI | Application | Type of dose | Dose          | Number of repetitions | Max individual dose | Max daily dose | Remarks | GR | Ref |
| 1 D - 10 D and < 8 kg   |  |    | REC         |              | 20 mg/kg/dose | 4 x daily             |                     | 80 mg/kg/day   |         | D  |     |
| 10 D - 18 Y and < 40 kg |  |    | REC         |              | 25 mg/kg/dose | 3 - 4 x daily         |                     | 100 mg/kg/day  |         | B  |     |

In the “General doses” window you see the information described in point d)5.2.1.

### d) 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 5.1).

| <b>Product</b>          | Dafalgan Supp 80 mg  |            |             |              |             |                       |                     |                |                |     |             |            |
|-------------------------|--|------------|-------------|--------------|-------------|-----------------------|---------------------|----------------|----------------|-----|-------------|------------|
| <b>Substance</b>        | Acetaminophen (Paracetamol)  |            |             |              |             |                       |                     |                |                |     |             |            |
| <b>Indication</b>       | fever, mild pain (pain score $\leq 3$ ), extended administration and outpatient sector |            |             |              |             |                       |                     |                |                |     |             |            |
| Calculated dose ▾       |  |            |             |              |             |                       |                     |                |                |     |             |            |
| General doses ▾         |  |            |             |              |             |                       |                     |                |                |     |             |            |
| Calculated dose ▲       |  |            |             |              |             |                       |                     |                |                |     |             |            |
| Age                     | Weight   | PI         | Application | Type of dose | Dose        | Number of repetitions | Max individual dose | Max daily dose | Remarks        | GR  | Ref         |            |
| 10 D - 18 Y and < 40 kg |  |            | REC         |              | 300 mg/dose | 3 - 4 x daily         |                     | 1'200 mg/day   |                | B   |             |            |
|                         | Date of birth  | 10.05.2015 | Weight      | 12 kg        | Height      | 92 cm                 | BMI                 | 14             | Preterm infant | Yes | GA at birth | 30 6/7 WOP |

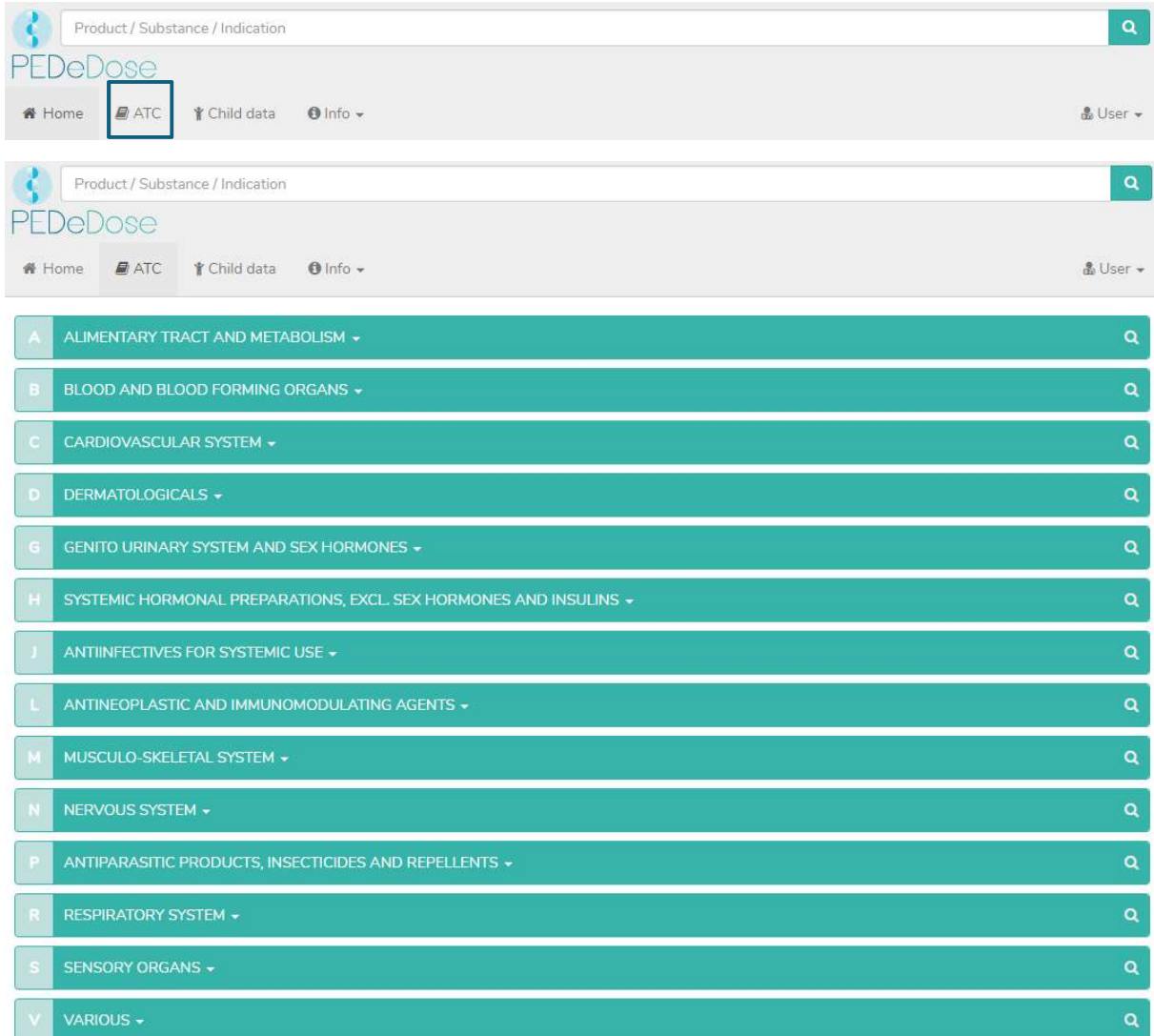
Below the section “Calculated dose”, the child data (date of birth, weight, height, preterm infant, GA (gestational age) at birth) are displayed.

In the “General remarks” window you see the information described in point g) 5.2.1.



### 5.3 ATC code

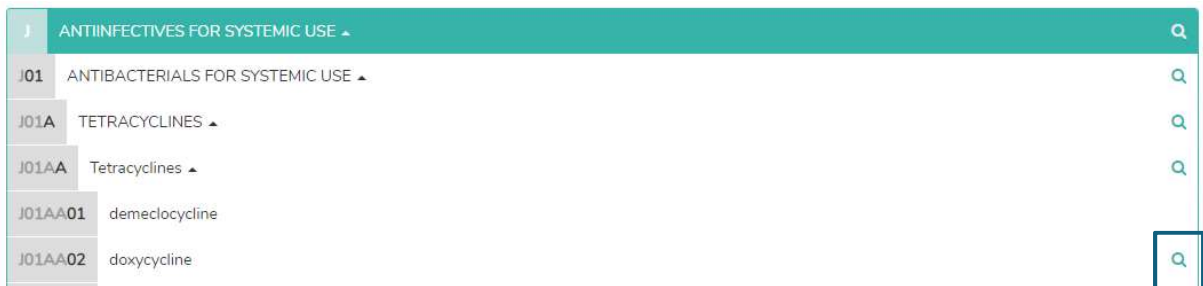
By clicking the “ATC” button at the top of the page, the ATC code selection drops down, see below.



The screenshot shows the PEDeDose interface with the ATC button highlighted. Below it, the ATC dropdown menu is open, displaying a list of 14 categories, each with a magnifying glass icon on the right:

- 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
- V VARIOUS

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



The screenshot shows the PEDeDose interface with the ATC dropdown menu open. The 'J ANTIINFECTIVES FOR SYSTEMIC USE' category is selected, and its sub-categories are displayed. The 'J01AA02 doxycycline' entry is highlighted, and a magnifying glass icon is visible on the right side of the dropdown menu.

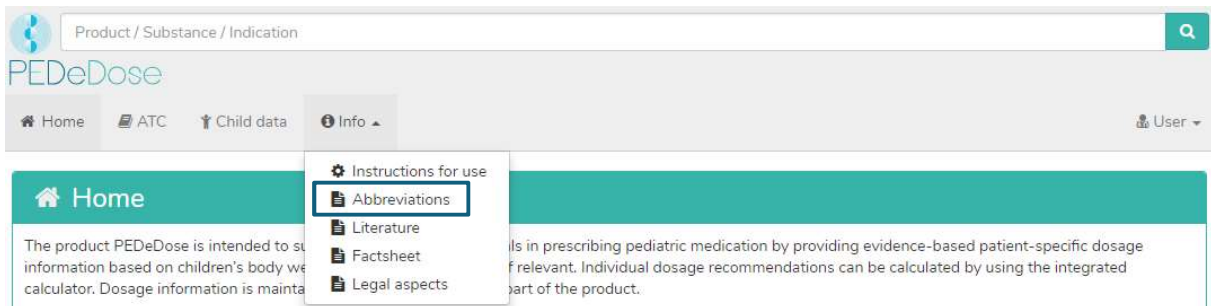
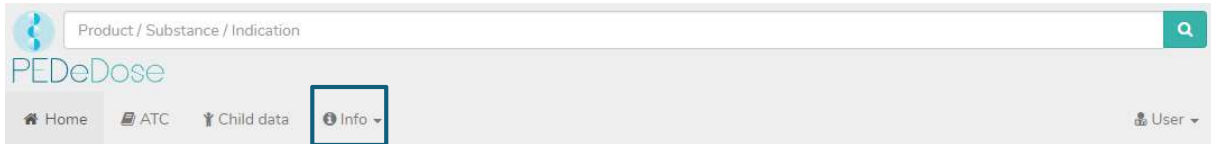
- J ANTIINFECTIVES FOR SYSTEMIC USE
- J01 ANTIBACTERIALS FOR SYSTEMIC USE
- J01A TETRACYCLINES
- J01AA Tetracyclines
- J01AA01 demeclocycline
- J01AA02 doxycycline

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



## 5.4 Abbreviations

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



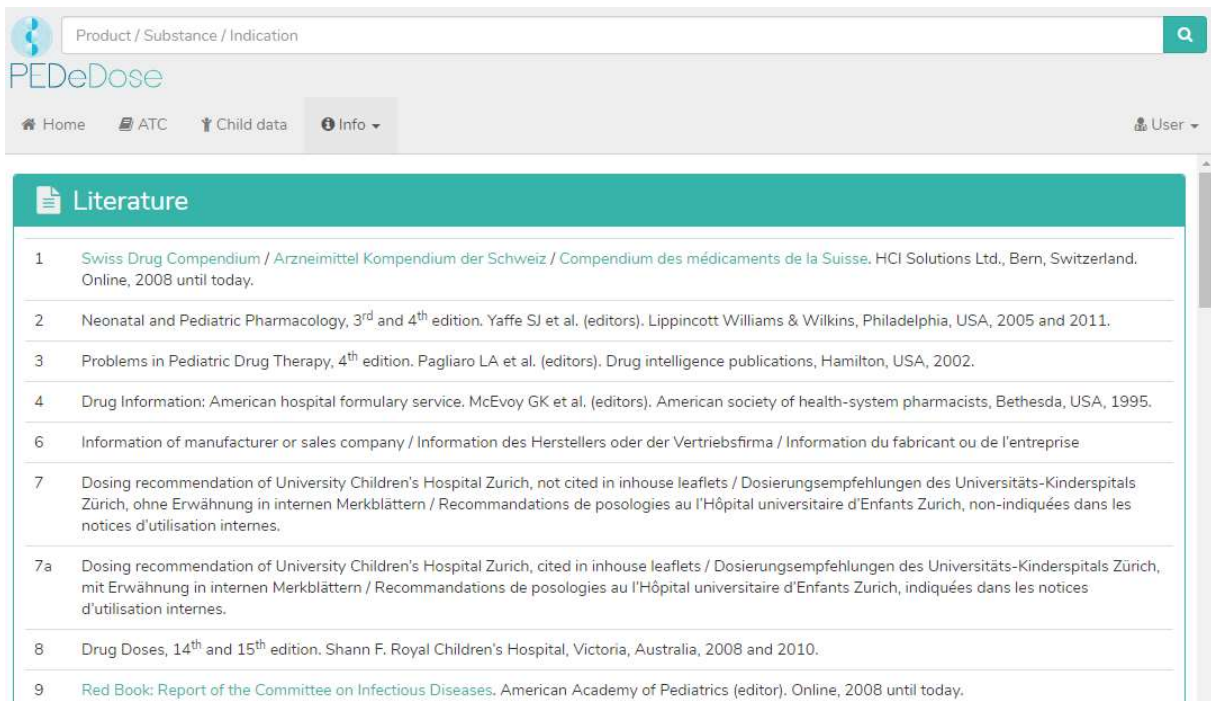
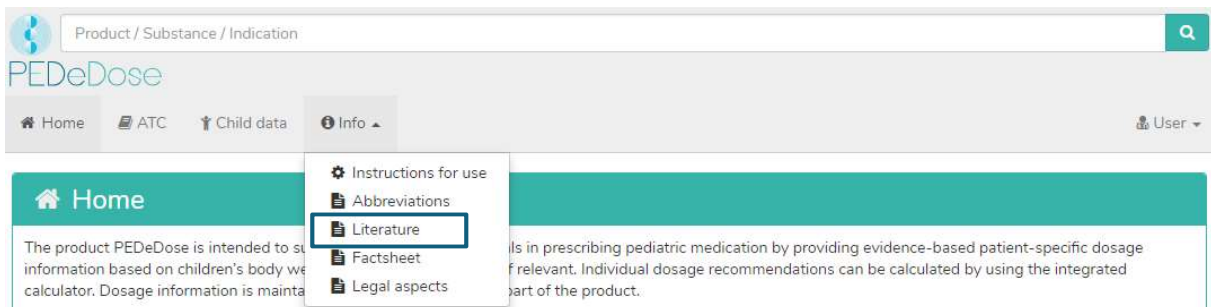
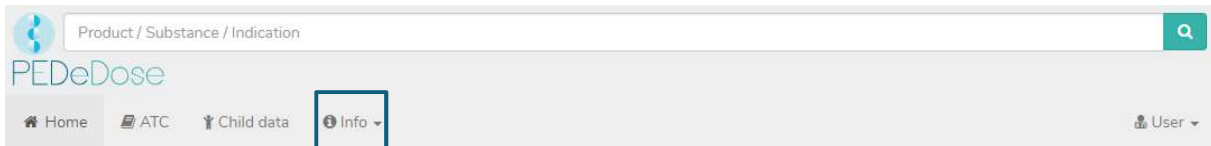
This screenshot shows the 'Abbreviations' page. It features a table with two columns: 'Abbreviations' and 'Description'. The table lists various medical abbreviations and their corresponding descriptions.

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

## 5.5 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 line refers to either the entire data set or only partial aspects of the data set.



## 6. Complaints and feedback

We kindly want to inform you that technical and content-related errors you have detected in PEDeDose have to be reported as soon as possible after detection to PEDEus via email ([info@pedeus.ch](mailto:info@pedeus.ch)).

## 7. Contact information





### 7.1 General data

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

### 7.2 Web addresses PEDeDose software

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

## 8. Primary label

|   |  |    |
|---|--|----|
|  | PEDEdose 2.1 2018  | CE |
|  |  |    |
|  |  |    |
|  | PEDEus<br>Technoparkstrasse 1<br>8005 Zurich<br>Switzerland<br><a href="http://www.pedeus.ch">www.pedeus.ch</a><br><a href="mailto:info@pedeus.ch">info@pedeus.ch</a><br><a href="http://www.pedeus.ch/">http://www.pedeus.ch/</a> |    |