

Instructions for use

PEDeDose

**Clinical Decision Support Tool for
Drug Dosages in Pediatrics 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" 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. 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 © 2018-2021 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

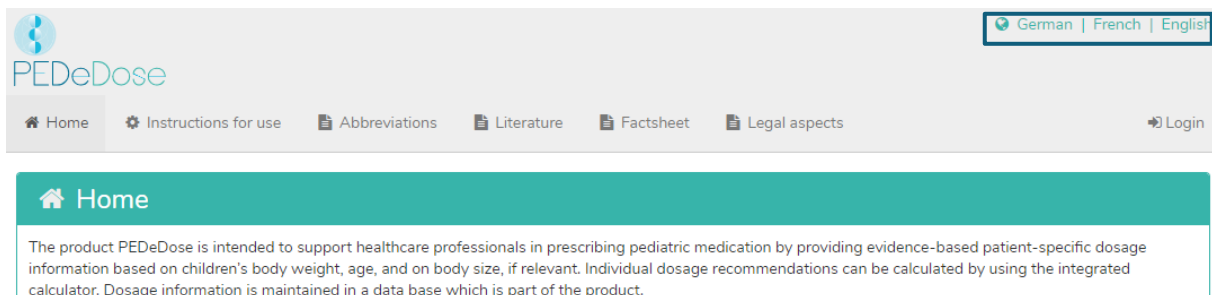
There are three different login processes: PEDeDose login, swiss-rx-login and IP-address login. With the PEDeDose and swiss-rx-login, the user must register upon first login and fill out a form about personal details. When logging in via the IP address, an institution receives direct access to the PEDeDose application for all 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 in accordance with the medical profession register of the Federal Office of Public Health (Switzerland).

1.4 Language

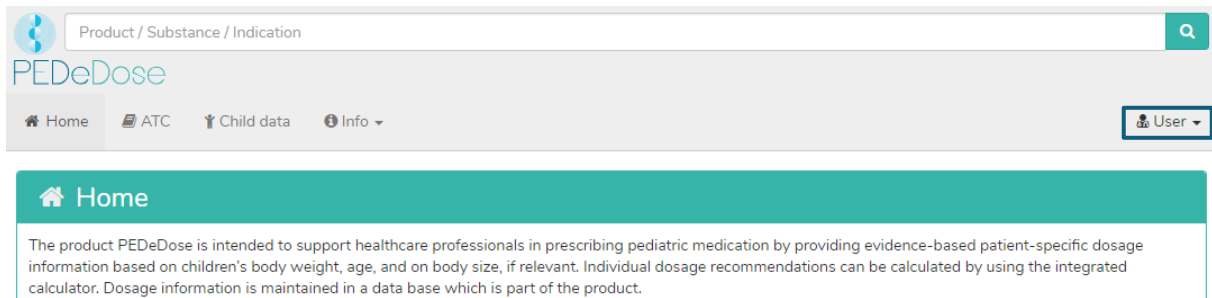
PEDeDose is available in German, French and English.

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

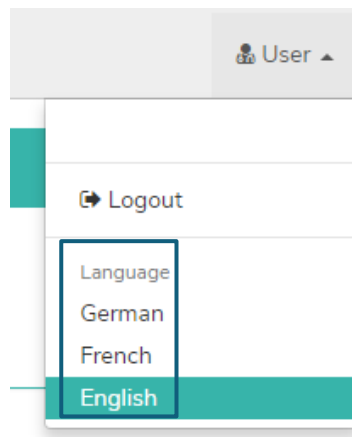


The screenshot shows the PEDeDose home screen. At the top right, there is a language selection menu with options for German, French, and English. Below the header, there is a navigation bar with links for Home, Instructions for use, Abbreviations, Literature, Factsheet, and Legal aspects, along with a Login button. The main content area is titled 'Home' and contains the following text: "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."

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.

The PEDeDose local installation serves in particular to ensure a high availability of the dosage data and the calculator, as it gives independence from a permanent internet connection.

These instructions for use apply for PEDeDose versions from 2.3.2 to 2.3.99 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 evidence-based, 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 newborns (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. doctors, 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

Not applicable

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

The following residual risks must be considered by the user:

- If a user enters incorrect data or (unintended) data is entered in PEDeDose 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, 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.
- As the system is based on IT technologies, performance may be affected by cybercrime.

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 section 0).

However, those dosages do not consider individual characteristics such as any limited 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 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 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 th 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 (preterm infants included, 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 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

2.3 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.

The following is an example of the explanations above:

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

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

The calculator in PEDeDose considers maximum dosages in the calculations.

2.4 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 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
Weight [kg]	0.25	200
Height [cm]	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^{1, 2} (weight and height). A warning is shown in case of weight and/or height below the 1st or above the 99th percentile. In preterm infants, a warning is shown in case of weight and/or height below the 3rd or above the 97th 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, "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.

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

² 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 37th 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 36th 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, 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. 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 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.

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 lines

Products that match the dosages are assigned to the individual dosage lines. 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 line. 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 lines 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 after processing by PEDeus in the respective institution. This is 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	↗
ALGIFOR Dolo forte Susp 400 mg/10ml	Ibuprofen	↗
ALGIFOR Dolo Junior 150 mg/7.5ml	Ibuprofen	↗
ALGIFOR Dolo Junior Susp 100 mg/5ml	Ibuprofen	↗
ALGIFOR Junior Susp 100 mg/5ml ★	Ibuprofen	↗
ALGIFOR Liquid Caps 400 mg	Ibuprofen	↗
ALGIFOR-L Filmtabl 200 mg	Ibuprofen	↗
ALGIFOR-L forte Filmtabl 400 mg	Ibuprofen	↗
ALGIFOR-L Gran 200 mg	Ibuprofen	↗

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

Search results for ibuprofen	
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 the active ingredient Ibuprofen).



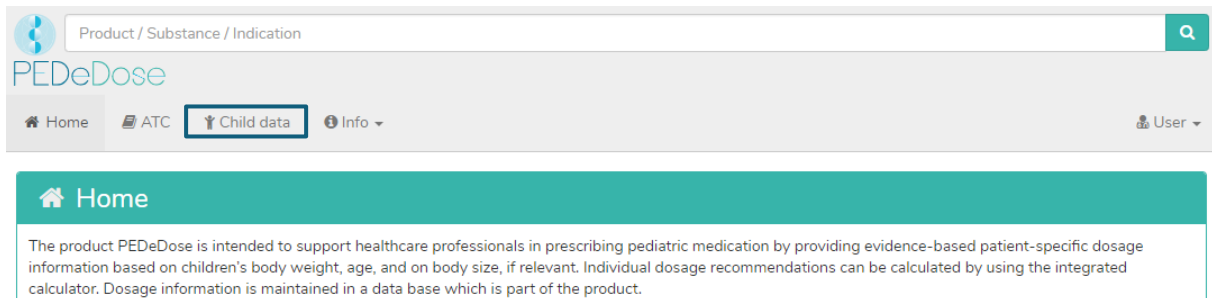
6.2 Printing

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

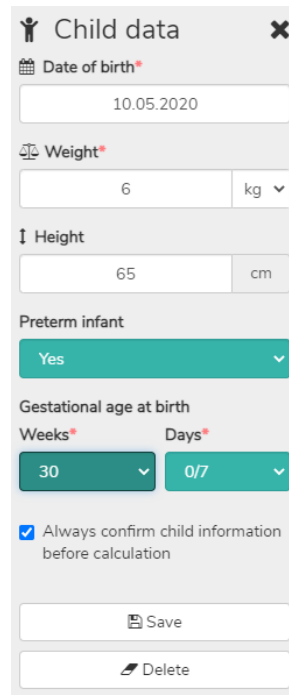
7.1 Child data

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.



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” in preterm infant)



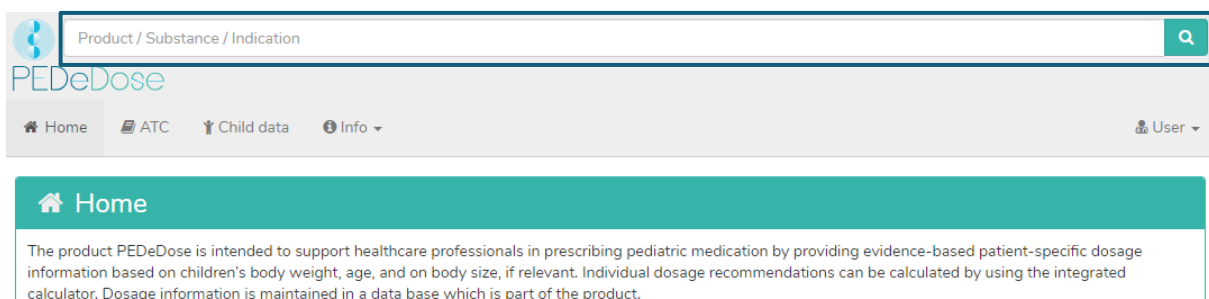
For preterm infants, select “Yes” in the field “Preterm infant”. Subsequently, the gestational age at birth is entered in weeks and days (see section 3.3).

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”). For systems accessing PEDeDose externally, this option can be turned off so that the user is not reaching 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

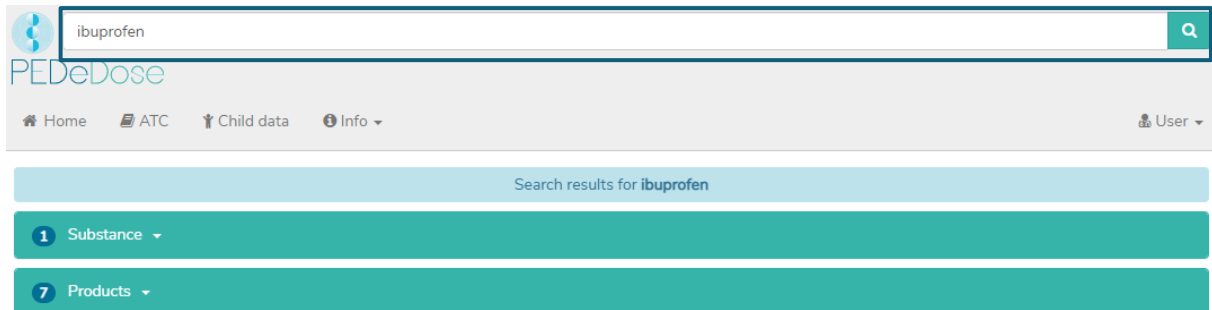
In the “Search” field, either a substance name, a drug indication or a product name can be entered; at least three letters or two letters (characters) and % can be entered. The search function is not case-sensitive.



7.2.1 Substance search

7.2.1.1 Substance

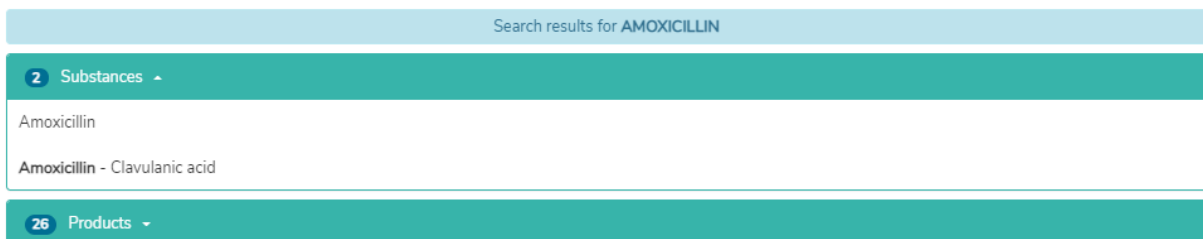
The substance name is entered in the “Search” field (e.g. Ibuprofen).



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 menu includes 'Home', 'ATC', 'Child data', and 'Info'. A 'User' dropdown menu is located on the right. Below the navigation, a light blue bar indicates 'Search results for ibuprofen'. Two teal bars show the search results: '1 Substance' and '7 Products'.

The search results are displayed below the “Search” field. For the example “Ibuprofen”, the search returned 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 indicated as fat 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 bar at the top indicates 'Search results for AMOXICILLIN'. Below it, a teal bar shows '2 Substances'. A white box lists the search results: 'Amoxicillin' and 'Amoxicillin - Clavulanic acid'. A second teal bar 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 (one indication for the selected example):



The screenshot shows the 'Indication' field for the substance 'Ibuprofen'. The 'Substance' field is filled with 'Ibuprofen'. The 'Indication' field is highlighted in blue and contains the text: 'analgesia (mild and moderate pain), fever, perioperative analgesia'.

7.2.1.3 Application

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

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

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 on the selected active substance, these are displayed below "General dosages"; see below (this includes e.g. dosage notes, attention remarks, contraindications).

Substance	Ibuprofen										
Indication	analgesia (mild and moderate pain), fever, 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
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		2 400 mg/day		A	
Substance specific remarks											
dosage note	In case of fever: can be administered alternating with paracetamol [70]. Perioperative analgesia: in combination with paracetamol [7a].										
attention	A good hydration of the patient is important. [152 (Algifor, 11/2019), 185]										
Qe-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)]										
9 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 (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 0)
Ref	Reference (number of reference on which the dosage is based), see “Literature” (chapter 7.5) for 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”. 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).)

The line 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 6 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).

Substance [Ibuprofen](#) Q
 Indication [analgesia \(mild and moderate pain\), fever, perioperative analgesia](#) Q
 Route of administration [PO, liquid](#)

Calculated dose 📅

General doses ❤️

Substance [Ibuprofen](#) Q
 Indication [analgesia \(mild and moderate pain\), fever, perioperative analgesia](#) Q
 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
3 Y 6 mth	12 kg		PO		84 - 120 mg/dose	3 x daily		360 mg/day	(A)		
3 Y 6 mth	12 kg		PO		60 - 84 mg/dose	4 x daily		360 mg/day	(A)		

👤 Date of birth 10.05.2017 Weight 12 kg Height 92 cm BMI 14 PI Yes GA 30 6/7 WOP chronA 3 Y 6 mth

7.2.1.6 Products in Switzerland

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



General doses ▾

Substance specific remarks

dosage note	In case of fever: can be administered alternating with paracetamol [70]. Perioperative analgesia: in combination with paracetamol [7a].
attention	A good hydration of the patient is important. [152 (Algifor, 11/2019), 185]
Qe-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)]

9 Products in Switzerland ▾

ALGIFOR Dolo forte Susp 200 mg/5ml	Ibuprofen	↗
ALGIFOR Dolo forte Susp 400 mg/10ml	Ibuprofen	↗
ALGIFOR Dolo Junior 150 mg/7.5ml	Ibuprofen	↗
ALGIFOR Dolo Junior Susp 100 mg/5ml	Ibuprofen	↗
ALGIFOR Junior Susp 100 mg/5ml	Ibuprofen	↗
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen	↗
IRFEN Junior Susp 100 mg/5ml	Ibuprofen	↗
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen	↗
OPTIFEN 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 in www.compendium.ch for the selected product, see below. To use the link from www.compendium.ch back to PEDeDose, the user must be logged in to www.compendium.ch.

9 Products in Switzerland ▾

ALGIFOR Dolo forte Susp 200 mg/5ml	Ibuprofen	↗
ALGIFOR Dolo forte Susp 400 mg/10ml	Ibuprofen	↗
ALGIFOR Dolo Junior 150 mg/7.5ml	Ibuprofen	↗
ALGIFOR Dolo Junior Susp 100 mg/5ml	Ibuprofen	↗
ALGIFOR Junior Susp 100 mg/5ml	Ibuprofen	↗
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen	↗
IRFEN Junior Susp 100 mg/5ml	Ibuprofen	↗
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen	↗
OPTIFEN Junior Susp 100 mg/5ml	Ibuprofen	↗

Below the "General doses" you will find a list of linked products in Switzerland that fit all or only certain dosage lines (3 products in the example below, click to select the list), while below the "Calculated dose" you will see only those products that fit the data set used for the calculation (1 product 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) 🔍
Indication fever, mild pain (pain score ≤3), extended administration and outpatient sector 🔍
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 D	3.5 kg		PO		35 - 53 mg/dose	4 x daily		210 mg/day		D	📄

⚡ **Date of birth** 27.11.2020 **Weight** 3.5 kg **Height** 50 cm **BMI** 14 **PI** No **chronA** 6 D

1 Product in Switzerland matching the data set of the 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
27 wk - 32 wk		PI	PO		10 - 12 mg/kg/dose	3 - 4 x daily		40 mg/kg/day		D	📄
32 wk - 40 wk		PI	PO		10 - 15 mg/kg/dose	4 x daily		60 mg/kg/day		D	📄
1 D - 10 D			PO		10 - 15 mg/kg/dose	4 x daily		60 mg/kg/day		D	📄
10 D - 6 mth			PO		20 - 22.5 mg/kg/dose	3 - 4 x daily		90 mg/kg/day		B	📄
6 mth - 18 Y and < 40 kg			PO		20 - 22.5 mg/kg/dose	3 - 4 x daily		90 mg/kg/day		B	📄

Substance specific remarks

Qe-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 “Product in Switzerland” field (ALGIFOR Junior Susp 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.

9 Products in Switzerland ▾		
ALGIFOR Dolo forte Susp 200 mg/5ml	Ibuprofen	↗
ALGIFOR Dolo forte Susp 400 mg/10ml	Ibuprofen	↗
ALGIFOR Dolo Junior 150 mg/7.5ml	Ibuprofen	↗
ALGIFOR Dolo Junior Susp 100 mg/5ml	Ibuprofen	↗
ALGIFOR Junior Susp 100 mg/5ml	Ibuprofen	↗
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen	↗
IRFEN Junior Susp 100 mg/5ml	Ibuprofen	↗
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen	↗
OPTIFEN Junior Susp 100 mg/5ml	Ibuprofen	↗

Produkt ALGIFOR Junior Susp 100 mg/5ml 🔍	↗
Wirkstoff Ibuprofen 🔍	

1 Indikation ▾

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

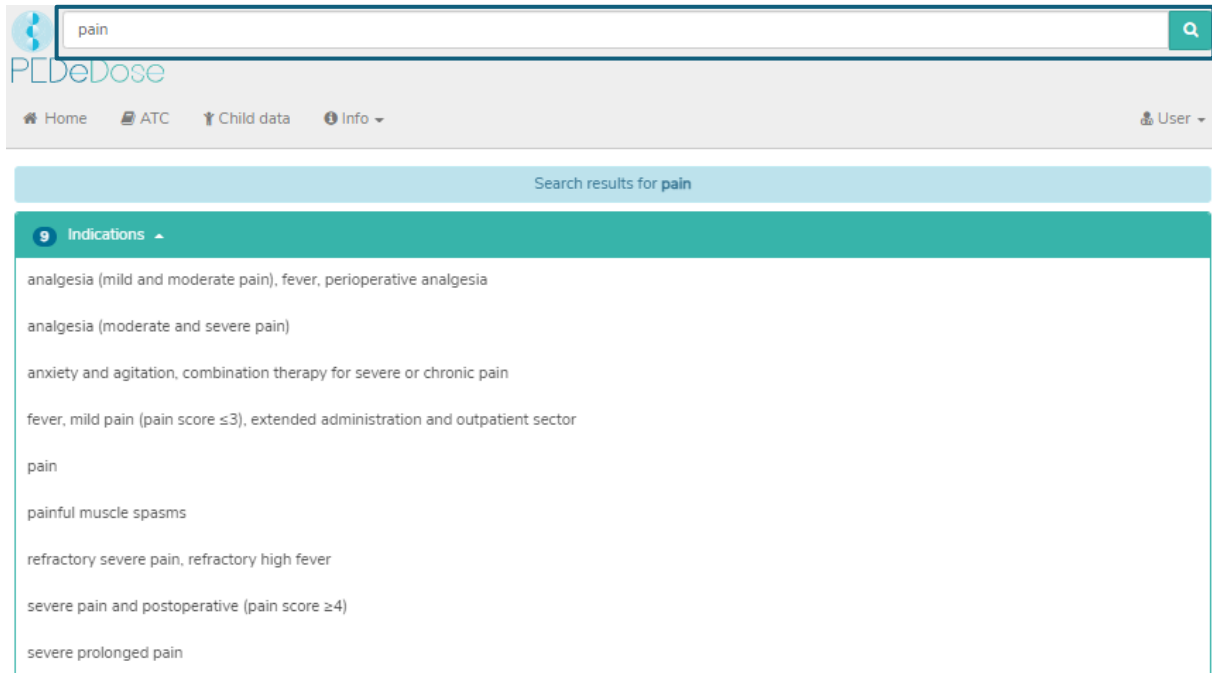
Produkt spezifische Bemerkungen	
Konzentration / Gehalt	20 mg/mL; 1 Flasche = 200 mL
Eigenschaften Produkt	Konservierungsmittel / Hilfsstoffe: enthält unter anderem Natriumbenzoat (E211), Aroma, Natriumcyclamat, Sorbitol, Saccharose (5 mL = 0.27 Obstwert = 11.8 kcal) [85 (03/2020), 152 (03/2020)]
Zubereitung	vor Gebrauch schütteln [1]
Anwendung	Haltbarkeit nach Zubereitung / Anbruch: 6 Mt Lagerung nach Zubereitung / Anbruch: bei RT lagern, nicht im KS Dosierhilfe: ML 2.5 mL und 5 mL (ML durch Oralspritze ersetzen) Geschmack: Orange Literatur Anwendung: 1, 6
Teilbarkeit / Sonde	Bemerkungen: Verabreichung über Magen-, Duodenal- und Jejunalsonde möglich Literatur Teilbarkeit / Sonde: 7
Zulassung	Zulassung bei Kindern: zugelassen ab 6 Mt [1]
Lagerung / Logistik	Lagerbedingungen: bei RT lagern [1]

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 are not “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).



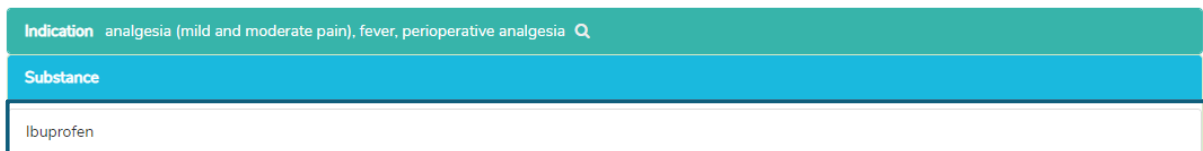
The screenshot shows the PEDeDose web application interface. At the top, there is a search bar with the text 'pain' and a magnifying glass icon. Below the search bar, the PEDeDose logo and navigation menu (Home, ATC, Child data, Info) are visible. The main content area displays 'Search results for pain' and a list of 9 indications under the heading 'Indications'. The indications listed are:

- analgesia (mild and moderate pain), fever, perioperative analgesia
- analgesia (moderate and severe pain)
- anxiety and agitation, combination therapy for severe or chronic pain
- fever, mild pain (pain score ≤3), extended administration and outpatient sector
- pain
- painful muscle spasms
- refractory severe pain, refractory high fever
- severe pain and postoperative (pain score ≥4)
- severe prolonged pain

The results are listed below the field “Indications” (9 results for the example pain).

7.2.2.2 Substance

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



The screenshot shows the 'Substance' field in the PEDeDose interface. The 'Indication' field is selected and displays 'analgesia (mild and moderate pain), fever, perioperative analgesia'. The 'Substance' field below it displays '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 should be applied 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 (route of administrations/galenic groups) see below.

Indication	analgesia (mild and 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 and moderate pain), fever, perioperative analgesia										
Substance	Ibuprofen										
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
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		2 400 mg/day		A	
Substance specific remarks											
dosage note	In case of fever: can be administered alternating with paracetamol [70]. Perioperative analgesia: in combination with paracetamol [7a].										
attention	A good hydration of the patient is important. [152 (Algifor, 11/2019), 185]										
Qe-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)]										
9 Products in Switzerland											

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

The line 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 6 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).

Indication analgesia (mild and moderate pain), fever, perioperative analgesia Q
Substance ibuprofen Q
Route of administration PO, liquid

Calculated dose 📅

General doses ❤️

Indication analgesia (mild and moderate pain), fever, perioperative analgesia Q
Substance ibuprofen Q
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
3 Y 6 mth	12 kg	PO			84 - 120 mg/dose	3 x daily		360 mg/day		(A)	📄
3 Y 6 mth	12 kg	PO			60 - 84 mg/dose	4 x daily		360 mg/day		(A)	📄
📄 Date of birth 10.05.2017 Weight 12 kg Height 92 cm BMI 14 PI Yes GA 30 6/7 WOP chronA 3 Y 6 mth											

7.2.2.6 Products in Switzerland

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

General doses ▾
🏠

Substance specific remarks

dosage note In case of fever: can be administered alternating with paracetamol [70]. Perioperative analgesia: in combination with paracetamol [7a].

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

Qe-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)]










9 Products in Switzerland ▾

ALGIFOR Dolo forte Susp 200 mg/5ml	Ibuprofen	🔗
ALGIFOR Dolo forte Susp 400 mg/10ml	Ibuprofen	🔗
ALGIFOR Dolo Junior 150 mg/7.5ml	Ibuprofen	🔗
ALGIFOR Dolo Junior Susp 100 mg/5ml	Ibuprofen	🔗
ALGIFOR Junior Susp 100 mg/5ml	Ibuprofen	🔗
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen	🔗
IRFEN Junior Susp 100 mg/5ml	Ibuprofen	🔗
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen	🔗
OPTIFEN 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 in www.compendium.ch for the selected product, see below. To use the link from www.compendium.ch back to PEDeDose, the user must be logged in to www.compendium.ch.

9 Products in Switzerland ▾		
ALGIFOR Dolo forte Susp 200 mg/5ml	ibuprofen	
ALGIFOR Dolo forte Susp 400 mg/10ml	ibuprofen	
ALGIFOR Dolo Junior 150 mg/7.5ml	ibuprofen	
ALGIFOR Dolo Junior Susp 100 mg/5ml	ibuprofen	
ALGIFOR Junior Susp 100 mg/5ml	ibuprofen	
IRFEN DOLO Junior Susp 100 mg/5ml	ibuprofen	
IRFEN Junior Susp 100 mg/5ml	ibuprofen	
OPTIFEN Dolo Junior Susp 100 mg/5ml	ibuprofen	
OPTIFEN Junior Susp 100 mg/5ml	ibuprofen	

Below the "General doses" you will find a list of linked products in Switzerland that fit all or only certain dosage lines (3 products in the example below, click to select the list), while below the "Calculated dose" you will see only those products that fit the data set used for the calculation (1 product in the example below, click to select the list).

Substance		Acetaminophen (Paracetamol) 									
Indication		fever, mild pain (pain score ≤3), extended administration and outpatient sector 									
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 D	3.5 kg		PO		35 - 53 mg/dose	4 x daily		210 mg/day		D	
	Date of birth	27.11.2020	Weight	3.5 kg	Height	50 cm	BMI	14	PI No	chronA	6 D
1 Product in Switzerland matching the data set of the 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
27 wk - 32 wk		PI	PO		10 - 12 mg/kg/dose	3 - 4 x daily		40 mg/kg/day		D	
32 wk - 40 wk		PI	PO		10 - 15 mg/kg/dose	4 x daily		60 mg/kg/day		D	
1 D - 10 D			PO		10 - 15 mg/kg/dose	4 x daily		60 mg/kg/day		D	
10 D - 6 mth			PO		20 - 22.5 mg/kg/dose	3 - 4 x daily		90 mg/kg/day		B	
6 mth - 18 Y and < 40 kg			PO		20 - 22.5 mg/kg/dose	3 - 4 x daily		90 mg/kg/day		B	

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 ▾

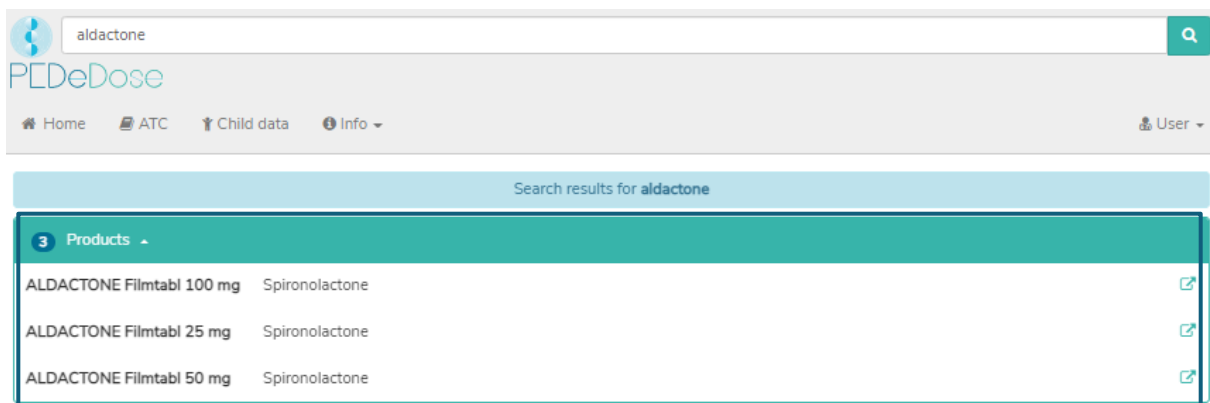
By clicking on the “Product in Switzerland” field and a product (ALGIFOR Junior Susp 100 mg/5ml in the example), the “Product-specific remarks” window opens, see section 7.2.1.7.

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 screenshot shows the PEDeDose search interface. At the top, there is a search bar with 'aldactone' entered. Below the search bar, the PEDeDose logo and navigation links (Home, ATC, Child data, Info) are visible. The search results are displayed under the heading 'Search results for aldactone'. A dropdown menu labeled '3 Products' is open, showing three results:

Product Name	Active Ingredient	Action
ALDACTONE Filmtabi 100 mg	Spironolactone	↗
ALDACTONE Filmtabi 25 mg	Spironolactone	↗
ALDACTONE Filmtabi 50 mg	Spironolactone	↗

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

7.2.3.2 Indication

By clicking on a product in the list (e.g. ALDACTONE film tabl 25 mg), the selection of indications is opened (one indication for the example ALDACTONE film tabl 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), Pfefferminzaroma [152 (03/2020)]

Pharmakodynamik Kontraindikationen: akute NI, Anurie, Hyperkaliämie, Morbus Addison [1]
Interaktionen: Digoxin [1]

Pharmakokinetik Q₀-Wert: 1

Teilbarkeit / Sonde Teilbarkeit: ja
Zermörsern: ja
Bemerkungen: Spironolacton ist sehr bitter.
Literatur Teilbarkeit / Sonde: 73, 74, 75, 76, 77

Zulassung Zulassung bei Kindern: zugelassen (Aldactone) [1]

Lagerung / Logistik Lagerbedingungen: bei RT lagern [1]

Sonstige Hinweise iv-Applikation siehe unter Canreonat (Soldactone)

Only in the German and French PEDeDose version of 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/storage). There are not “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, see below.

Product ALDACTONE Filmtabl 25 mg 🔍
Substance Spironolactone 🔍
Indication heart failure, edema 🔍

Calculated dose 📅

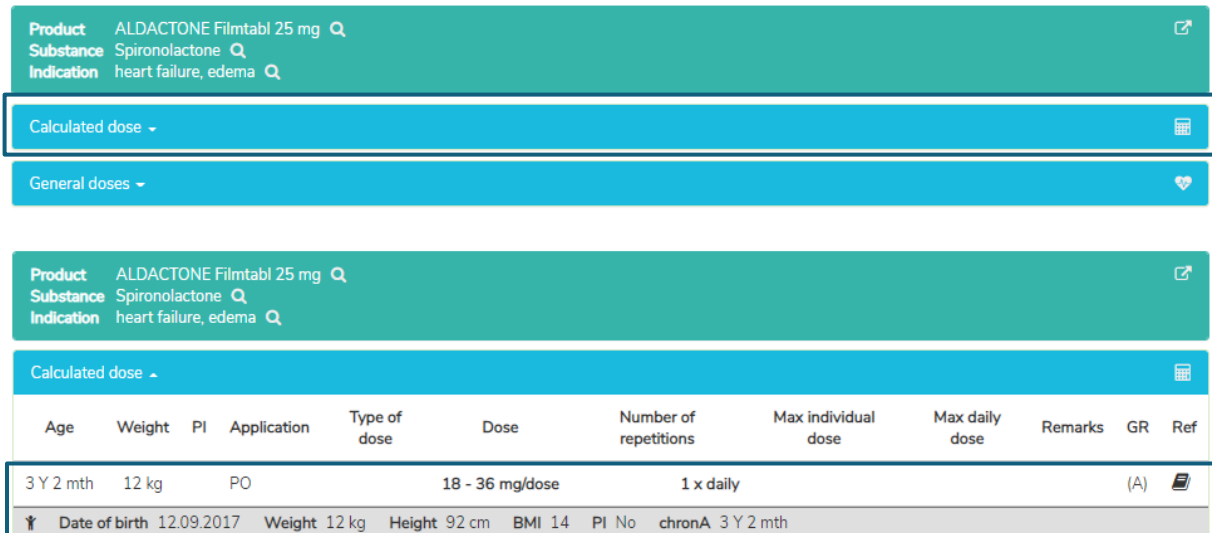
General doses ⌵

Age/PMA	Weight	PI	Application	Type of dose	Dose	Number of repetitions	Max individual dose	Max daily dose	Remarks	GR	Ref
28 D - 18 Y and < 50 kg			PO		1.5 - 3 mg/kg/dose	1 x daily				(A)	📄
≥ 18 Y or ≥ 50 kg			PO		25 - 200 mg/dose	1 x daily		400 mg/day	dose depends on indication, see information for healthcare professionals; daily dose can be split into several doses	A	📄

In the “General doses” window you see the information described in point 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	PI	Application	Type of dose	Dose	Number of repetitions	Max individual dose	Max daily dose	Remarks	GR	Ref
3 Y 2 mth	12 kg	PO			18 - 36 mg/dose	1 x daily				(A)	

↑ Date of birth 12.09.2017 Weight 12 kg Height 92 cm BMI 14 PI No chronA 3 Y 2 mth

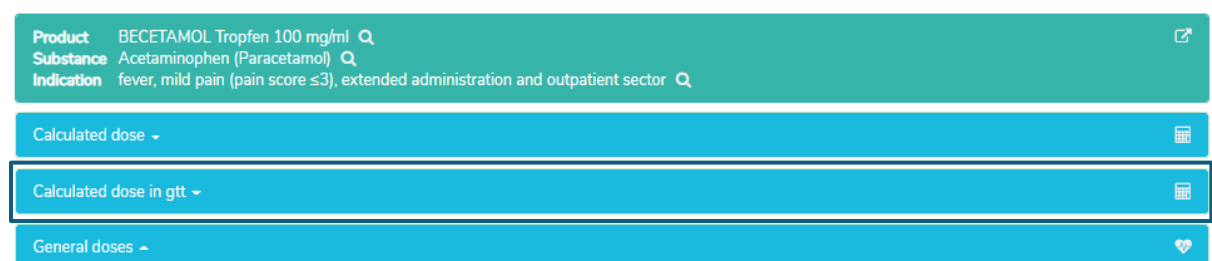
The line of the individually calculated dose shows the age and weight of the child for whom the dose has been calculated (in the example above "3 Y 2 mth", "12 kg").

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).

In the “Product-specific remarks” window you see the information described in point 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
Substance Acetaminophen (Paracetamol)
Indication fever, mild pain (pain score ≤3), extended administration and outpatient sector

Calculated dose

Calculated dose in gtt

General doses

Product BECETAMOL Tropfen 100 mg/ml
Substance Acetaminophen (Paracetamol)
Indication fever, mild pain (pain score ≤3), extended administration and outpatient sector

Calculated dose

Calculated dose in gtt

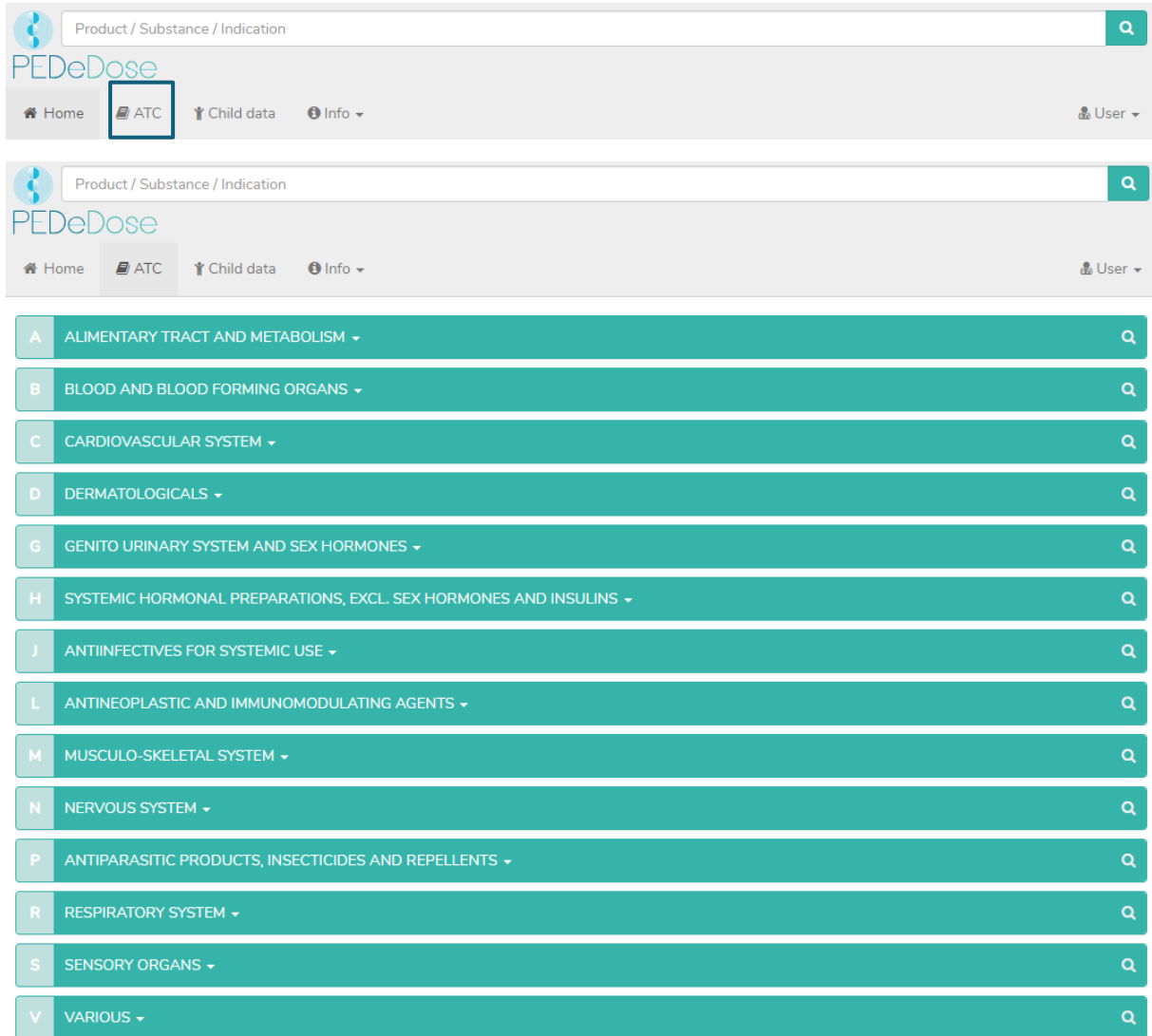
General doses

By clicking on the field "Calculated dose in drops (gtt)" the dose line for the individually calculated dose in drops (gtt) opens in addition to the individually calculated dose, see below.

Product BECETAMOL Tropfen 100 mg/ml											
Substance Acetaminophen (Paracetamol)											
Indication fever, mild pain (pain score ≤3), extended administration and outpatient sector											
Calculated dose											
Age	Weight	PI	Application	Type of dose	Dose	Number of repetitions	Max individual dose	Max daily dose	Remarks	GR	Ref
7 wk	4.5 kg		PO		90 - 101 mg/dose	3 - 4 x daily		405 mg/day		B	
📅 Date of birth		15.10.2020	📊 Weight		4.5 kg	📊 Height		55 cm	📊 BMI		15
			📊 PI		No	📊 chronA		7 wk			
Calculated dose in gtt											
Age	Weight	PI	Application	Type of dose	Dose	Number of repetitions	Max individual dose	Max daily dose	Remarks	GR	Ref
7 wk	4.5 kg		PO		18 - 20 gtt/dose	3 - 4 x daily		81 gtt/day		B	
📅 Date of birth		15.10.2020	📊 Weight		4.5 kg	📊 Height		55 cm	📊 BMI		15
			📊 PI		No	📊 chronA		7 wk			

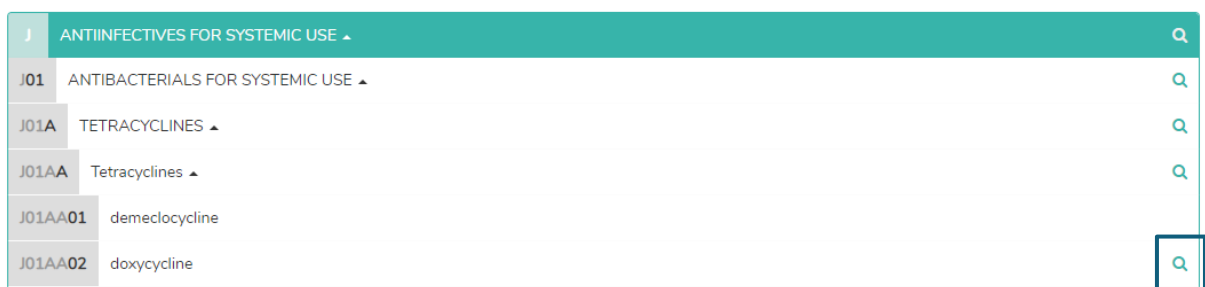
7.3 ATC code

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. The 'ATC' button is highlighted with a red box. Below the navigation menu, 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 button on the right (magnifying glass), the substances (and if applicable, products) can be selected, see below.

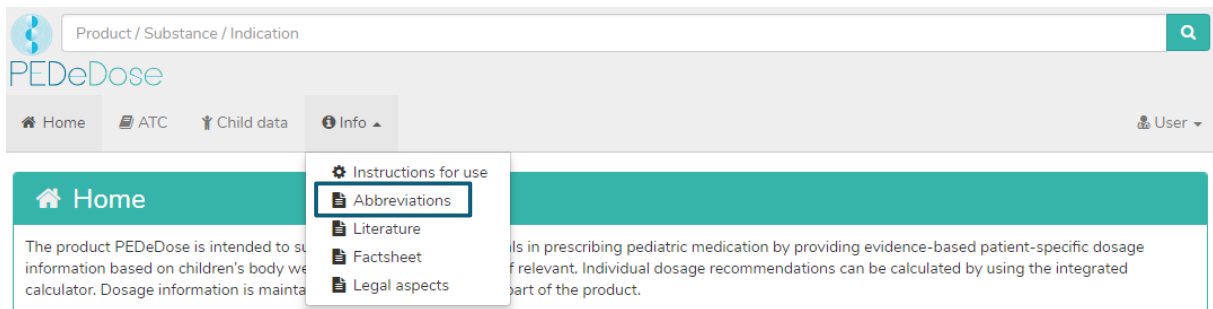
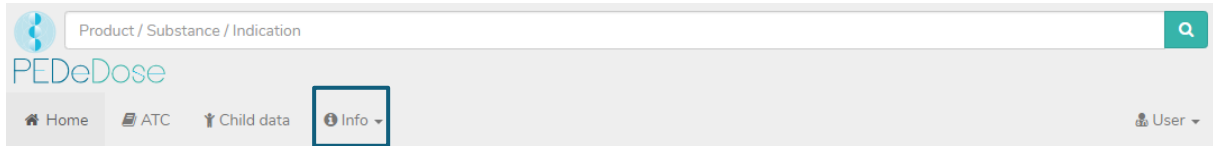
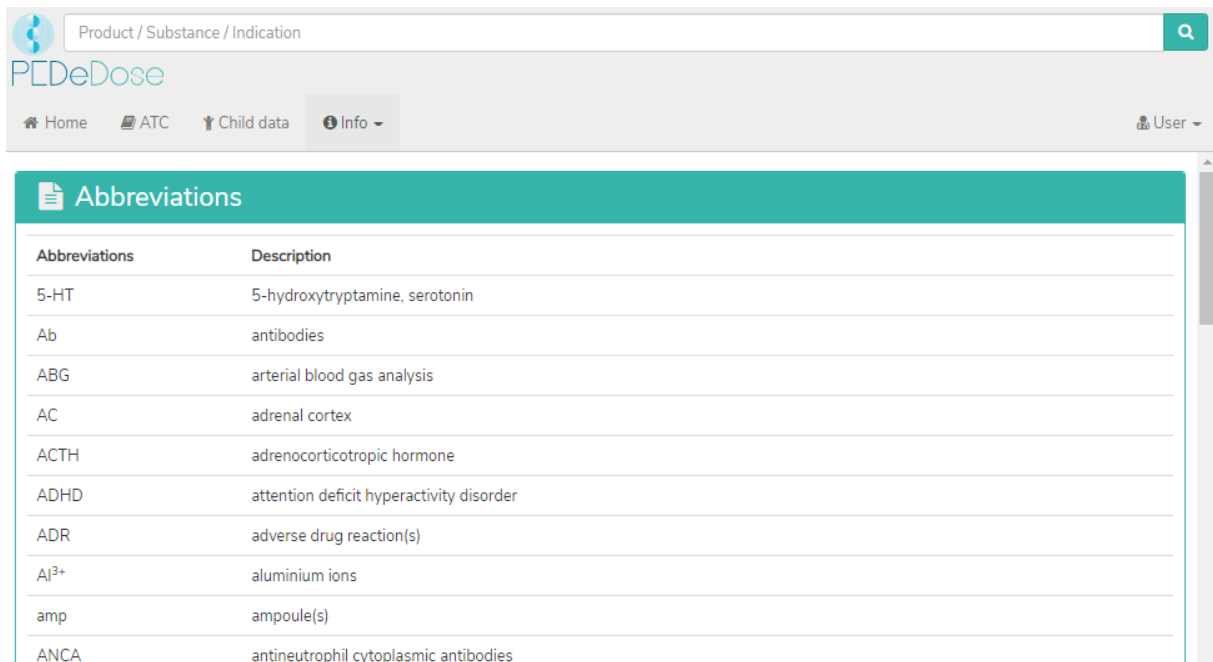


The screenshot shows the expanded ATC dropdown menu. The 'J ANTIINFECTIVES FOR SYSTEMIC USE' category is selected and highlighted in teal. Below it, a list of sub-categories is displayed. Each sub-category has a magnifying glass icon on the right. The sub-categories listed are: J01 ANTIBACTERIALS FOR SYSTEMIC USE, J01A TETRACYCLINES, J01AA Tetracyclines, J01AA01 demeclocycline, and J01AA02 doxycycline. The magnifying glass icon for the J01AA02 doxycycline entry is highlighted with a red box.

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 “Abbreviation” page, which lists all the abbreviations used in PEDeDose, see below.

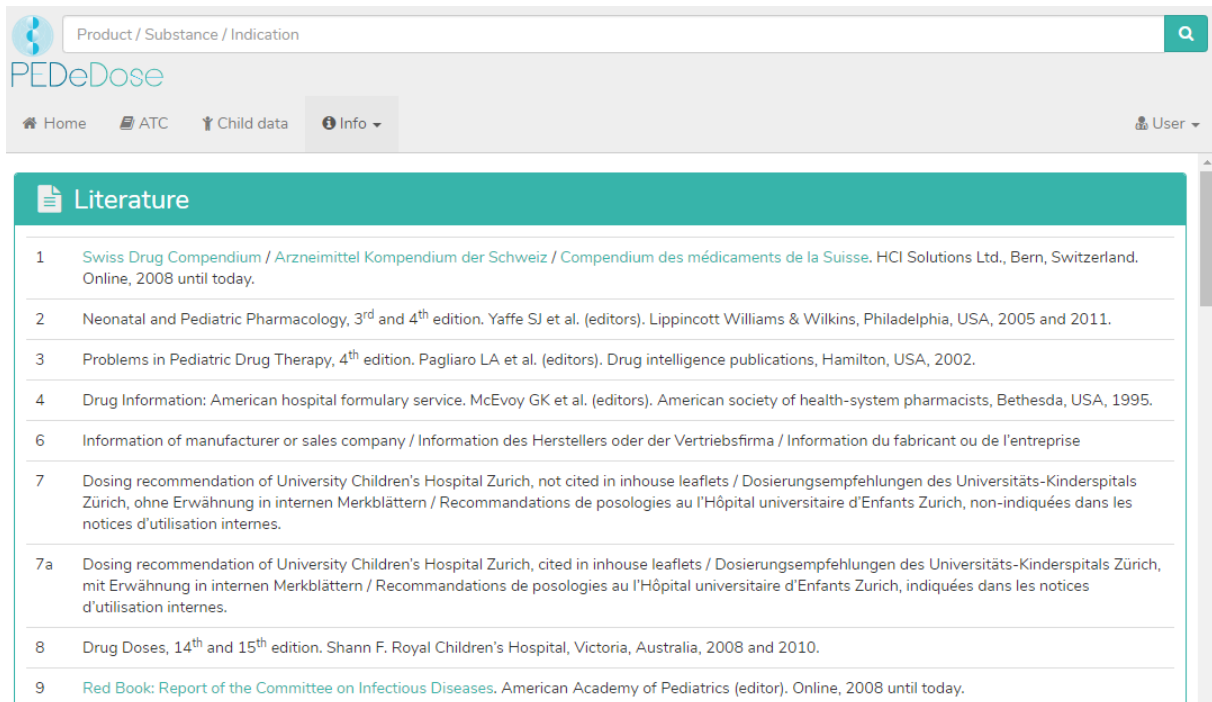
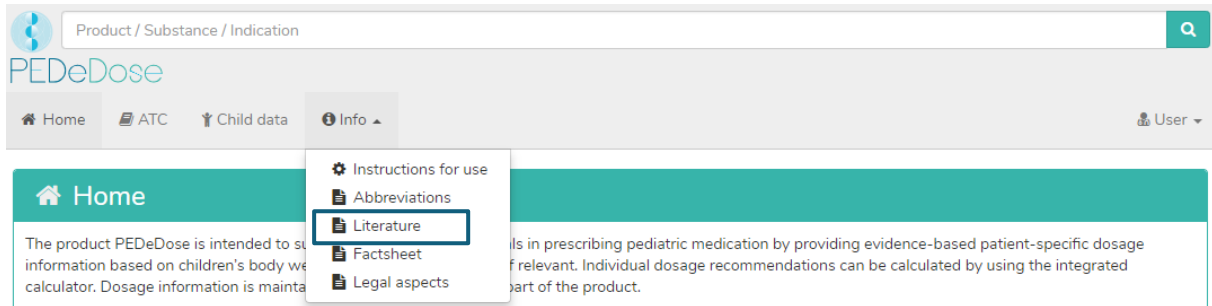
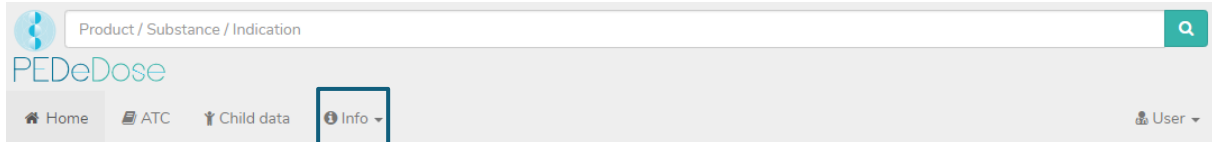
The screenshot displays the 'Abbreviations' page, which features a table listing various abbreviations and their corresponding descriptions. The table has two columns: 'Abbreviations' and 'Description'.

Abbreviations	Description
5-HT	5-hydroxytryptamine, serotonin
Ab	antibodies
ABG	arterial blood gas analysis
AC	adrenal cortex
ACTH	adrenocorticotrophic hormone
ADHD	attention deficit hyperactivity disorder
ADR	adverse drug reaction(s)
Al ³⁺	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 line 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 PEDeDose have to be reported immediately, but no later than 48 hours after detection to PEDeus via email (info@pedeus.ch). 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
+41 (0)44 521 73 80

9.2 Web addresses PEDeDose application








- www.pededose.ch (main address)
- www.pededose.net
- 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 2.3	
	12-2020	
	12-2025	
	Available at: https://www.pededose.ch/	
UDI-PI:	Available at: https://www.pededose.ch/	
	PEDeus AG Technoparkstrasse 1 8005 Zurich Switzerland info@pedeus.ch https://www.pedeus.ch/	CHRN: CHE341324507
	European authorized representative: Johner Medical GmbH Niddastrasse 91 60329 Frankfurt am Main Germany	SRN: 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.