



# **Instructions for use**

# **PEDeDose**

**Pediatric Dosages 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 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.

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 individualized data.

PEDeDose provides pediatric dosage information in three languages (German, French, English). Dosages are displayed via a search for active ingredient, 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" of the medication concerned. 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 (not 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 IFU is always available on [www.pededose.ch](http://www.pededose.ch). In order to guarantee the timeliness of the IFU, this should not be printed out or, if done so, at the user's own responsibility.

### 1.1 Copyright

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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. Access to the product is restricted by state of the art login solutions possible in the domain (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 on the Swiss market via swiss-rx-login. The website ([www.pededose.ch](http://www.pededose.ch)) is ready to use immediately after a successful login.

An access via IP address or a local installation may be used. For further information, contact PEDEus.

## **1.3 Login**

There are three different possibilities of login processes: PEDeDose login, swiss-rx-login and IP-address login.

### **1.3.1 PEDeDose login**

Clicking the “login” button will open a new window. When attempting a login for the first time, the user must click on “request new login”, complete the form that appears and save the data. The user must then follow the instructions and will receive an e-mail when the account is activated. Afterwards, the user can freely log in to PEDeDose.

### **1.3.2 Swiss-rx-login**

By clicking “swiss-rx-login.ch” the user will be redirected to the swiss-rx website, where the user needs to follow the instructions and is then redirected back to PEDeDose and logged in. (If not, the user must click again on “swiss-rx-login.ch” and will be logged in). The user will be prompted to enter additional information on the PEDeDose website. The account is activated after the form is completely filled in and submitted.

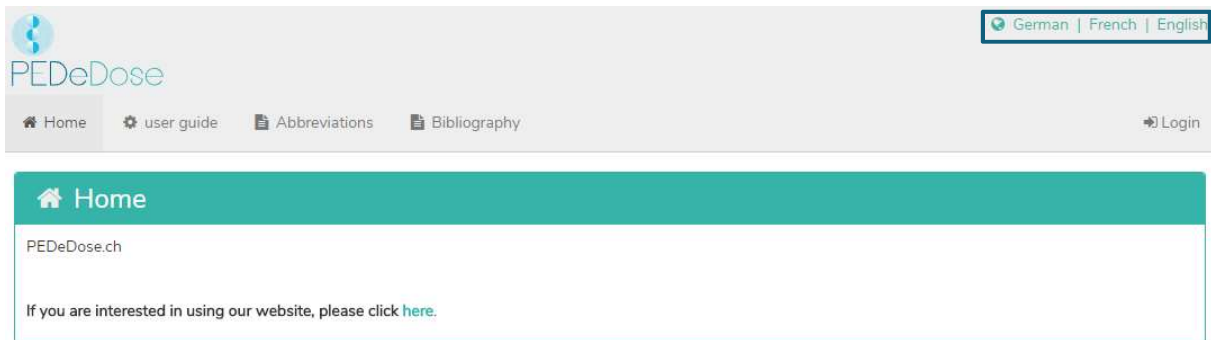
### **1.3.3 IP-address login**

Via IP-address login, an institution can gain direct access to the PEDeDose website for all computers using this address. The IP-address login is activated after communication of the IP-address and signing a corresponding contract between a requesting institution and PEDEus and is intended for a larger number of PEDeDose users (e.g. hospitals, pharmacies). Online access to the PEDeDose website via an enabled IP address automatically logs the user on.

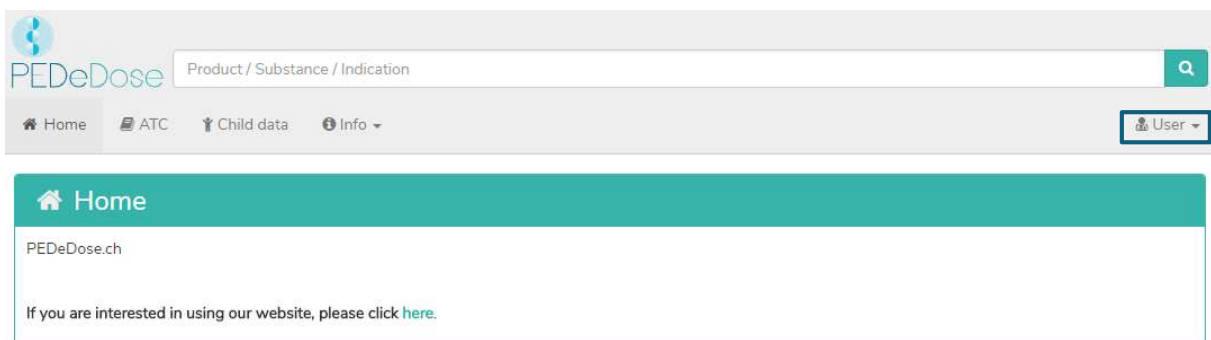
## **1.4 Language**

PEDeDose is available in German, French and English.

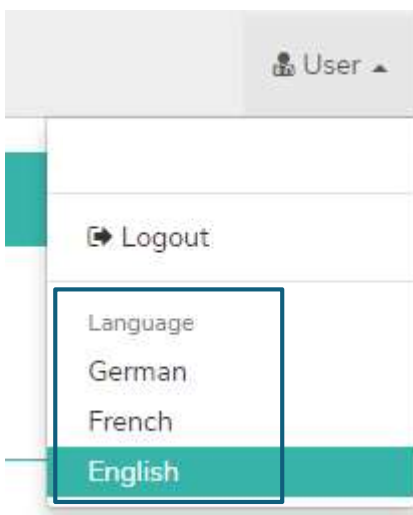
The language is selected on the top right of the home screen, (see below):



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 the user to install an anti-virus software on their system.

PEDeDose runs on the most common internet browsers (e.g. chrome, explorer, safari, etc., 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 by 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 03 applies for PEDeDose versions from 2.0.3 through 2.0.99 and replaces the previous version.

## 1.6 Residual risks

The following residual risks must be considered by the user:

- If a user enters incorrect input or (unintended) input is made in PEDeDose by another person without the user’s knowledge, the received output might be incorrect.
- It may be that PEDeDose is temporarily unavailable or partially unavailable, or the update will run 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 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.

## 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 doses

In the database, maximum individual and/or daily doses are indicated to some extent. The interpretation of maximum doses is difficult with children. If the main dose is given per kg body weight, whereas the maximum dose is given as a fixed dose without reference to body weight, this maximum dose must be interpreted as follows: The main dosage is valid up to the body weight ("limit") where the maximum dose is reached. If the child weighs less than this "limit", the maximum dose must not be applied. If the child weighs more, it will no longer be dosed per kg of body weight, but the maximum dose 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 randomized controlled trial (RCT); well-planned, single randomized controlled study; All-or-nothing principle, (approval by the Swiss authorities since 01/01/2011)
(A)	Systematic review of randomized controlled trial (RCT); well-planned, single randomized 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"

## 3. Calculation

If the user uses the PEdeDose version without calculator, this section will not apply to them.

### 3.1 Dosage calculation

The PEdeDose website allows the calculation of dosages for a child after entering date of birth, body weight and - if necessary - height. In addition, it automatically displays the dosage for the appropriate age group. 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 error message 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.

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

### 3.3 Calculation of preterm infant dosages

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 neonate 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 IFU is for users of the web service. The web service provides access to PEDeDose via an application developed by clinical information systems. The web service allows the user to either calculate a dosage after entering the substance or the product or check back a self-selected dosage.

The user of the web service is responsible for the timeliness of the child information. 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 back check

The web service allows the user to check back a self-selected dosage and indicates the deviation from the calculated dosage in percent. If the defined, active substance-dependent tolerance – differentiated 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	OK/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 last column (toxic/black) may be shown together with “Dangerous/Red”.

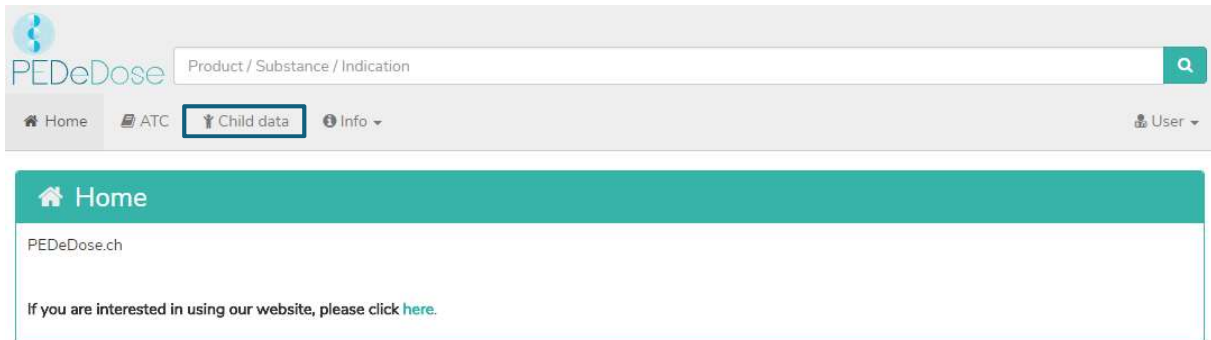
If PEDeDose is specified in ranges, the highest (for upper limits) or the lowest value (for lower limits) is used for the tolerance calculation.

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

## 5. Detailed instructions for use

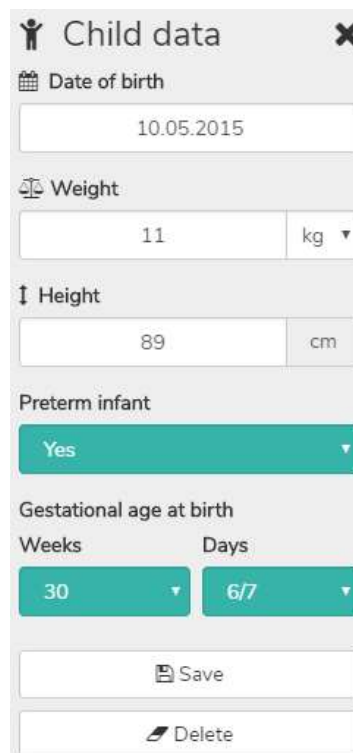
### 5.1 Child data

Clicking on “Child data” opens a window in which you can enter information concerning the child for which 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 the dose calculation)
- preterm infant (yes or no)
- gestational age at birth (weeks and days, only after clicking “yes” in preterm infant)

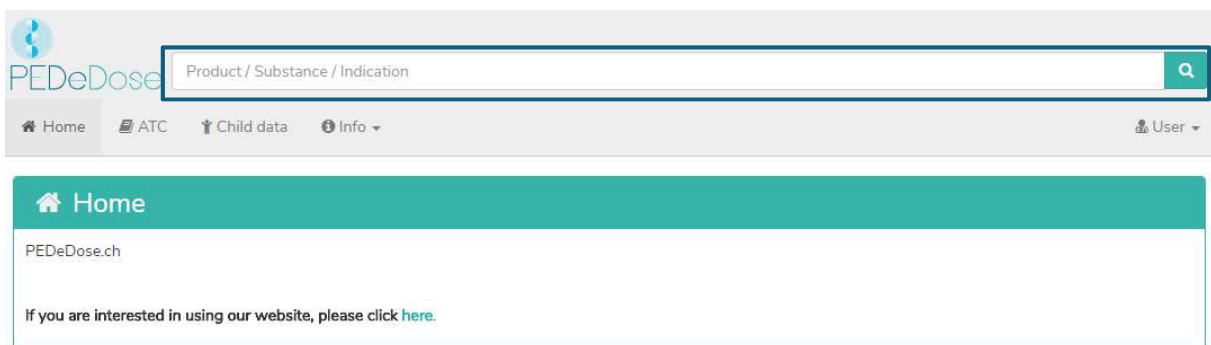


For preterm infants, select “Yes” in the field “Preterm infant”. Subsequently, the gestational age at birth is entered in weeks and days (see section 3.3).

The entered data are 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.

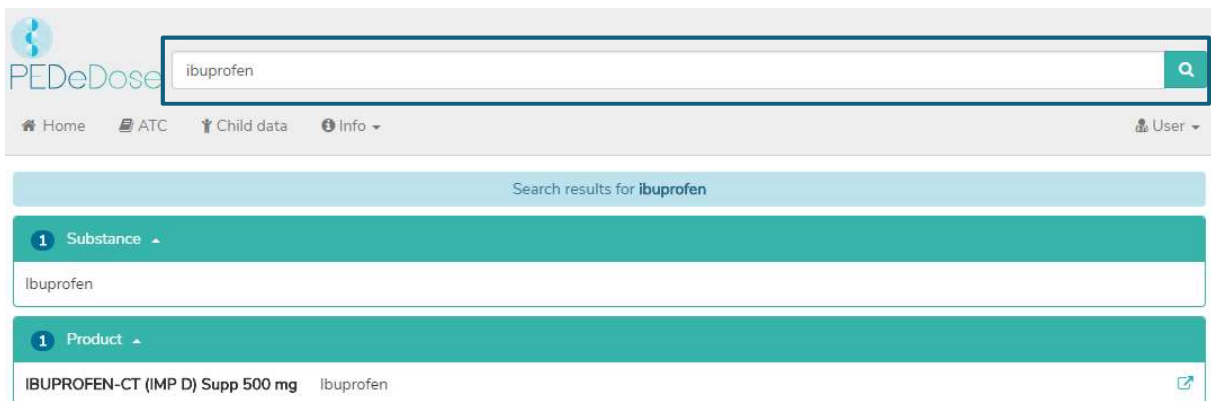


The screenshot shows the PEDeDose website interface. At the top left is the PEDeDose logo. A search bar is prominently displayed with the placeholder text "Product / Substance / Indication" and a magnifying glass icon on the right. Below the search bar is a navigation menu with links for Home, ATC, Child data, and Info. A user profile icon labeled "User" is in the top right corner. The main content area below the navigation menu shows a "Home" header and a message: "If you are interested in using our website, please click [here](#)."

### 5.2.1 Substance search

#### a) Substance

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



The screenshot shows the PEDeDose website interface with the search bar containing the text "ibuprofen". Below the search bar, the search results are displayed. The results are organized into two sections: "Substance" and "Product". The "Substance" section shows one result: "Ibuprofen". The "Product" section shows one result: "IBUPROFEN-CT (IMP D) Supp 500 mg 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):

<b>Substance</b> Ibuprofen
<b>Indication</b>
analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia

### c) Application / route of administration

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

<b>Substance</b> Ibuprofen
<b>Indication</b>
analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia
po, flüssig
po, Brause- und lösliche Form
po, Tabletten, Dragées, Kapseln
rec

### d) General Doses

Clicking on an application (i.e. “po, flüssig”) 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, flüssig											
<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	Res
6 M - 11 Y and 5 - 40 kg			po		7 - 10 mg/kg/dose	3 x daily		30 mg/kg/day		(A)	
6 M - 11 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)	
<b>1</b> Product 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 “Bibliography” (chapter 5.5) for reference list. The “book symbol” works as a “mouseover 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, flüssig

Calculated Dose ▾

General Doses ▾

1 Product in Switzerland ▾

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

Calculated Dose ▲

Age	Weight	PI	Application	Type of dose	Dose	Number of repetitions	Max individual dose	Max daily dose	Remarks	GR	Ref
6 M - 11 Y and 5 - 40 kg			po		77 - 110 mg/dose	3 x daily		330 mg/day		(A)	
6 M - 11 Y and 5 - 40 kg			po		55 - 77 mg/dose	4 x daily		330 mg/day		(A)	
Date of birth	10.05.2015	Weight	11 kg	Height	89 cm	Pre-term 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), see below.

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

Calculated Dose ▾

General Doses ▾

1 Product in Switzerland ▲

ALGIFOR Junior Susp 100 mg/5ml Ibuprofen

By clicking on the button on the right in the field “Product in Switzerland” the prescribing information 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, flüssig

Calculated Dose ▾

General Doses ▾

1 Product in Switzerland ▾

ALGIFOR Junior Susp 100 mg/5ml    ibuprofen

### g) General Remarks

By clicking on the “Product in Switzerland” field (ALGIFOR Junior Susp 100 mg/5ml in the example), the “General Remarks” window opens, 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, flüssig

Calculated Dose ▾

General Doses ▾

1 Product in Switzerland ▾

ALGIFOR Junior Susp 100 mg/5ml    ibuprofen



<b>Product</b>	Algifor Junior Susp 100 mg/5ml
<b>Substance</b>	Ibuprofen

1 Indication -

analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia

**General Remarks**

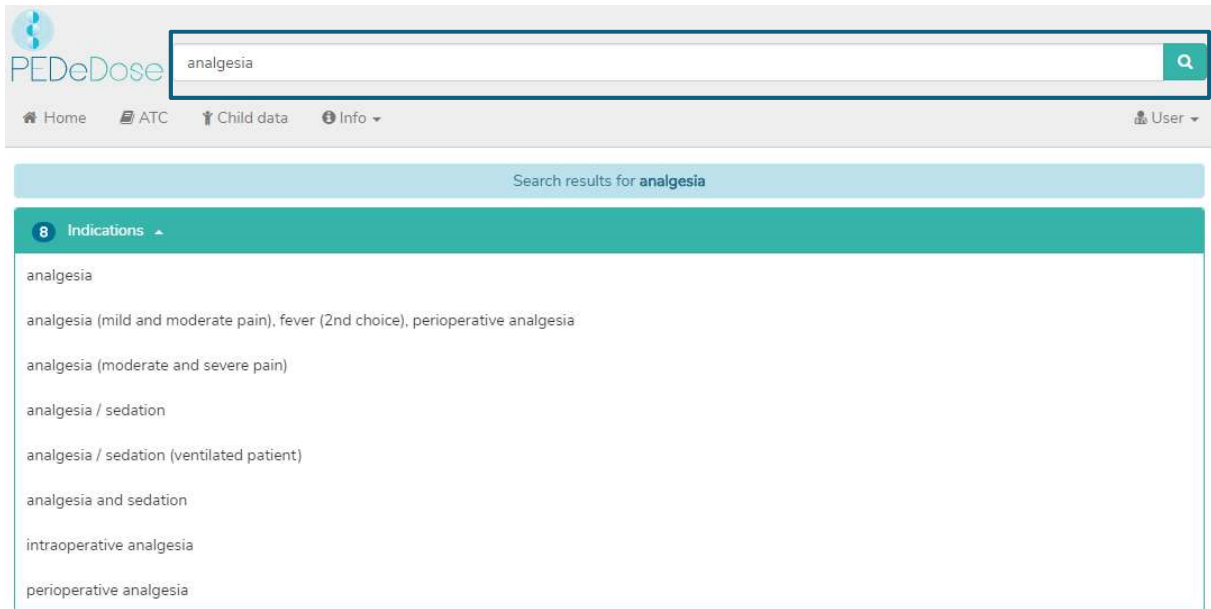
<b>Konzentration / Gehalt</b>	20 mg/mL; 1 Flasche = 200 mL
<b>preservatives / excipients</b>	Natriumbenzoat (E211), Aromatica, Natriumcyclamat, Sorbitol, Saccharose [1, 85]
<b>contraindications</b>	aktive GI-Ulcera oder GI-Blutungen, entzündliche Darmerkrankungen wie Morbus Crohn oder Colitis ulcerosa, Schwere HI, LI oder NI, hereditäre Fructose-Intoleranz (Sorbitol), Patienten unter antikoagulatorischer Therapie mit Acetylsalicylsäure (z.B. Aspirin Cardio, Aspegic), Dehydratation [1, 7] interactions: andere NSAR, Glucocorticoide, orale Antikoagulantien, Digoxin, Phenytoin, Methotrexat, Baclofen, Chinolone [1 (Algifor)], niedrigdosierte Acetylsalicylsäure (es kann auf Diclofenac ausgewichen werden) [122]
<b>Duration of drug effect</b>	Q <sub>0</sub> -value: 1
<b>application / intake</b>	vor Gebrauch schütteln [1]
<b>dosing aid</b>	durability after preparation / opening: 6 Mt storage after preparation / opening: bei RT lagern, nicht im KS ML 2.5 mL und 5 mL (ML durch Oralspritze ersetzen) graduation marks: (ML durch Oralspritze ersetzen) taste: Orange references: 1, 6
<b>suspend / dissolve</b>	remarks: Verabreichung über Magen-, Duodenal- und Jejunalsonde möglich references: 7
<b>approved for the use in children</b>	zugelassen ab 6 Mt [1]
<b>storage conditions</b>	bei RT lagern [1]
<b>other notes</b>	Bei Fieber: kann alternierend zu Paracetamol verabreicht werden. [70]Perioperative Analgesie: in Kombination mit Paracetamol [7:97]
<b>acute overdosage</b>	q0 values: 1

In the “General Remarks” window you find information about the selected product, for instance preservatives, contraindications, concentration, dosing aids. This information is available only in German and French. “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.

## 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 left is the PEDeDose logo. A search bar contains the text 'analgesia' with a magnifying glass icon to its right. Below the search bar is a navigation menu with 'Home', 'ATC', 'Child data', and 'Info' (with a dropdown arrow), and a 'User' profile icon on the right. Below the navigation is a header for 'Search results for analgesia'. A teal bar indicates '8 Indications'. A list of search results is displayed below:

- 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 PEDeDose interface. A teal bar at the top displays the selected indication: 'Indication analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia'. Below this, a blue bar is labeled 'Substance'. A white text input field below the blue bar 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 gives back substances and products, which might be applied in a specific clinical situation.

### c) Application / route of administration

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

<b>Indication</b>	analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia
<b>Substance</b>	ibuprofen
	po, flüssig
	po, Brause- und lösliche Form
	po, Tabletten, Dragées, Kapseln
	rec

#### d) General Doses

Clicking on an application (example “po, flüssig”) opens the “General Doses” window, see below.

<b>Indication</b>	analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia										
<b>Substance</b>	ibuprofen										
<b>Route of administration</b>	po, flüssig										
<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 M - 11 Y and 5 - 40 kg			po		7 - 10 mg/kg/dose	3 x daily		30 mg/kg/day		(A)	
6 M - 11 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)	
1 Product in Switzerland											

In the “General Doses” window you see the information described under point d)5.2.1.

#### 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 shown. (Two lines are displayed in the example below because there are two different numbers of repetitions (3 x daily and 4 x daily).)

<b>Indication</b>	analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia										
<b>Substance</b>	ibuprofen										
<b>Route of administration</b>	po, flüssig										
<b>Calculated Dose</b>											
<b>General Doses</b>											
1 Product in Switzerland											

<b>Indication</b>	analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia										
<b>Substance</b>	Ibuprofen										
<b>Route of administration</b>	po, flüssig										
<b>Calculated Dose</b> ▾											
Age	Weight	PI	Application	Type of dose	Dose	Number of repetitions	Max individual dose	Max daily dose	Remarks	GR	Ref
6 M - 11 Y and 5 - 40 kg			po		77 - 110 mg/dose	3 x daily		330 mg/day		(A)	
6 M - 11 Y and 5 - 40 kg			po		55 - 77 mg/dose	4 x daily		330 mg/day		(A)	
<b>↑ Date of birth</b>	10.05.2015	<b>Weight</b>	11 kg	<b>Height</b>	89 cm	<b>Pre-term infant</b>	Yes	<b>GA at birth</b>	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 route of administration (example ibuprofen, oral, liquid), see below.

<b>Indication</b>	analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia										
<b>Substance</b>	Ibuprofen										
<b>Route of administration</b>	po, flüssig										
<b>Calculated Dose</b> ▾											
<b>General Doses</b> ▾											
<b>1 Product in Switzerland</b> ▾											
ALGIFOR Junior Susp 100 mg/5ml Ibuprofen											

By clicking on the button on the right in the field “Product in Switzerland” the prescribing information is opened for the selected product, see below.

<b>Indication</b>	analgesia (mild and moderate pain), fever (2nd choice), perioperative analgesia										
<b>Substance</b>	Ibuprofen										
<b>Route of administration</b>	po, flüssig										
<b>Calculated Dose</b> ▾											
<b>General Doses</b> ▾											
<b>1 Product in Switzerland</b> ▾											
ALGIFOR Junior Susp 100 mg/5ml Ibuprofen											

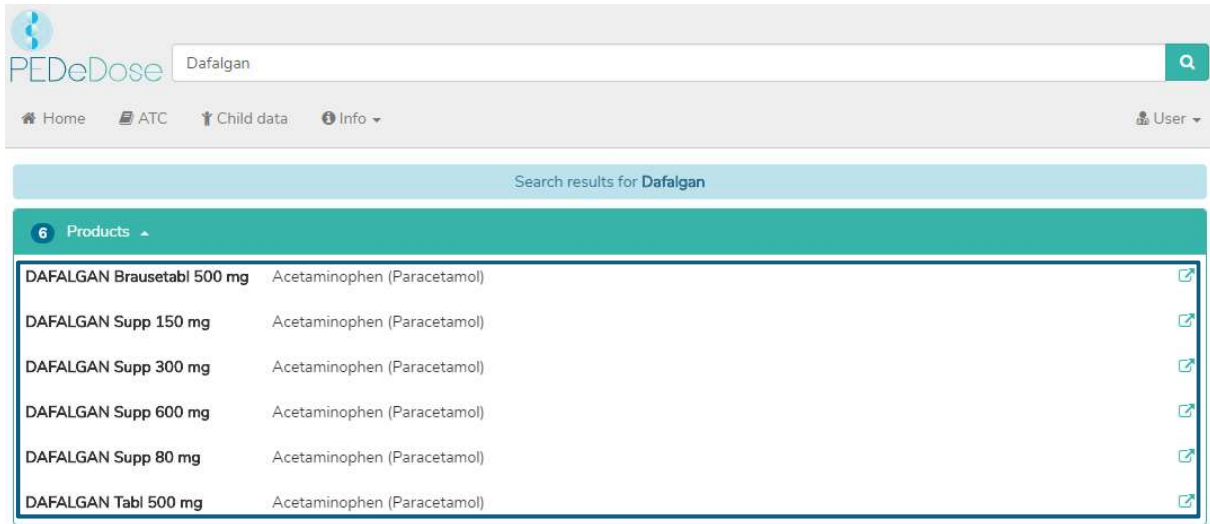
By clicking on the “Product in Switzerland” field (ALGIFOR Junior Susp 100 mg/5ml in the example), the “General Remarks” window opens, see section g) 5.2.1.

### 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).

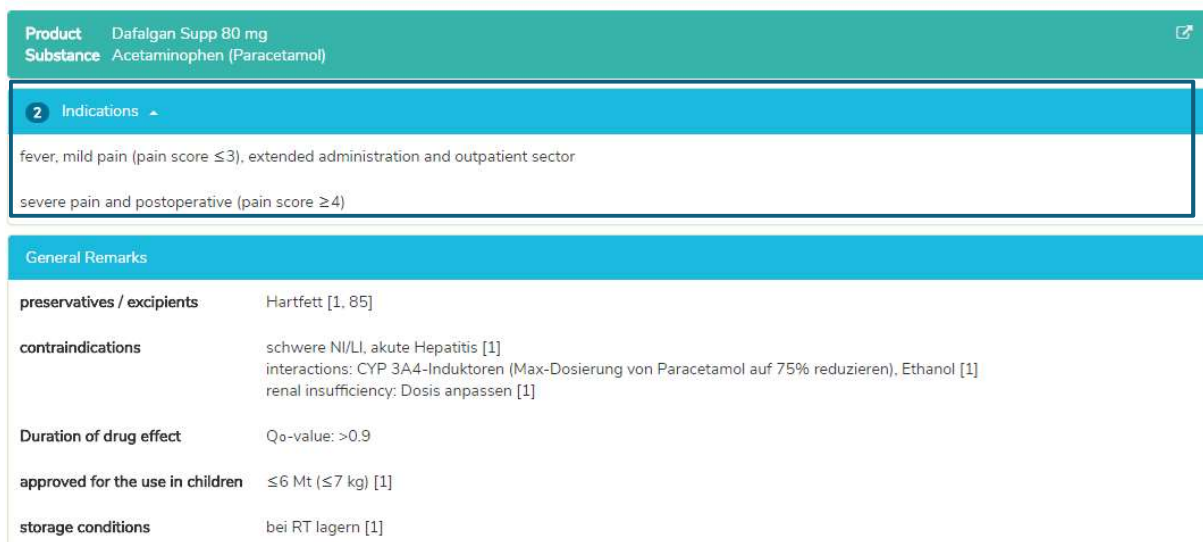


Search results for Dafalgan	
<b>6 Products</b>	
DAFALGAN Brausetabl 500 mg	Acetaminophen (Paracetamol)
DAFALGAN Supp 150 mg	Acetaminophen (Paracetamol)
DAFALGAN Supp 300 mg	Acetaminophen (Paracetamol)
DAFALGAN Supp 600 mg	Acetaminophen (Paracetamol)
DAFALGAN Supp 80 mg	Acetaminophen (Paracetamol)
DAFALGAN Tabl 500 mg	Acetaminophen (Paracetamol)

The search results for Dafalgan are listed below the heading “Products”, see picture above (six 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):



<b>Product</b>	Dafalgan Supp 80 mg
<b>Substance</b>	Acetaminophen (Paracetamol)
<b>2 Indications</b>	
	fever, mild pain (pain score ≤3), extended administration and outpatient sector
	severe pain and postoperative (pain score ≥4)
<b>General Remarks</b>	
<b>preservatives / excipients</b>	Hartfett [1, 85]
<b>contraindications</b>	schwere NI/LI, akute Hepatitis [1] interactions: CYP 3A4-Induktoren (Max-Dosierung von Paracetamol auf 75% reduzieren), Ethanol [1] renal insufficiency: Dosis anpassen [1]
<b>Duration of drug effect</b>	Q <sub>0</sub> -value: >0.9
<b>approved for the use in children</b>	≤6 Mt (≤7 kg) [1]
<b>storage conditions</b>	bei RT lagern [1]

Below the indications you can find the “General remarks” regarding the selected product. In this field, additional information about the selected product is displayed (e.g. preservatives, excipients, contraindications).

### 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 doses 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
< 10 D			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 under 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 ▾											
General Remarks											
<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 ▾											
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		275 mg/dose	3 - 4 x daily		1'100 mg/day		B	
<b>Date of birth</b>	10.05.2015	<b>Weight</b>	11 kg	<b>Height</b>	89 cm	<b>Pre-term infant</b>	Yes	<b>GA at birth</b>	30 6/7 WOP		

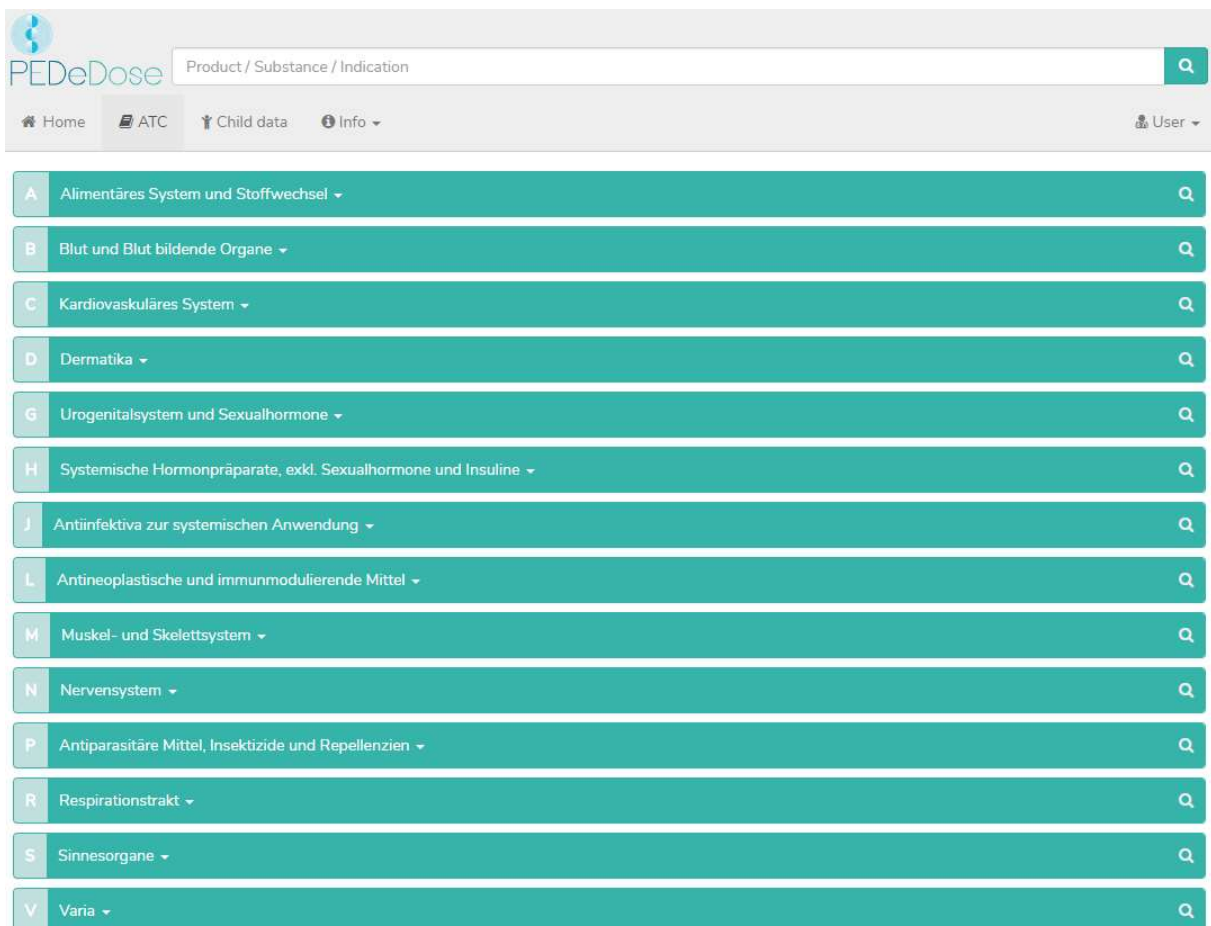
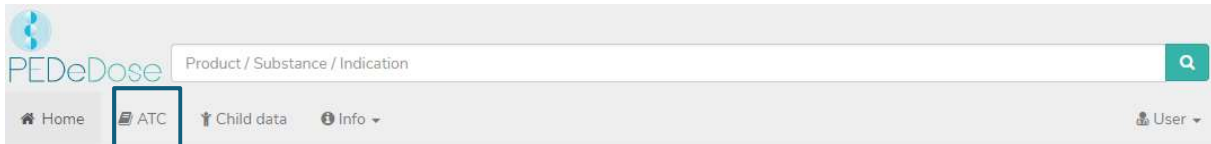


Below the section “Calculated Dose”, the child data (date of birth, weight, height, preterm infant, GA (gestational age) at birth) are displayed.

In the “General Remarks” window you see the information described under point g) 5.2.1.

### 5.3 ATC

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



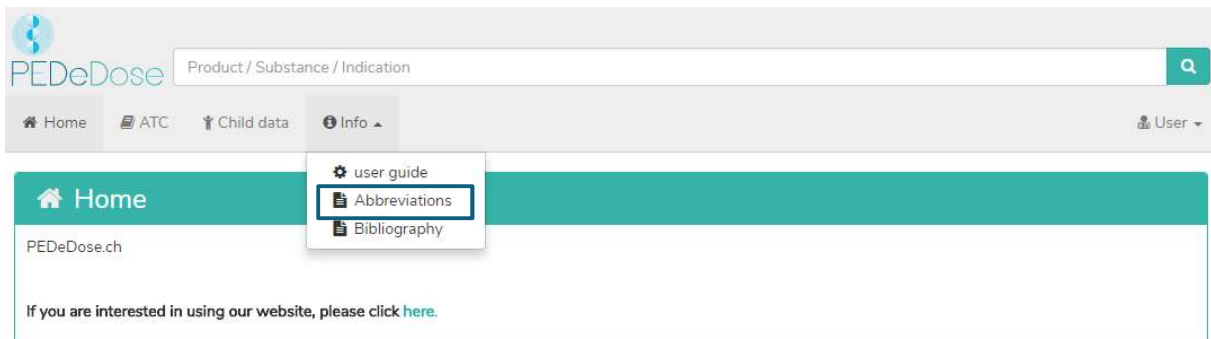
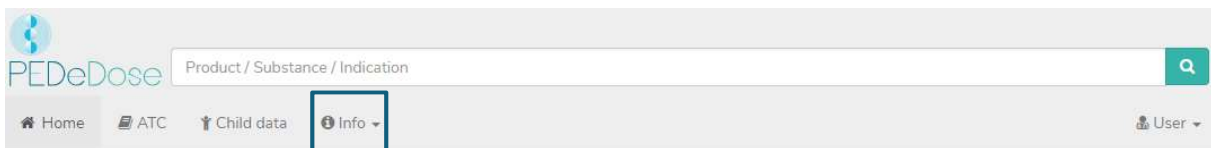
Select the appropriate path to go to the substance of interest. By clicking on the button on the right (magnifying glass), the substances (and if applicable, products) can be selected, see below.



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

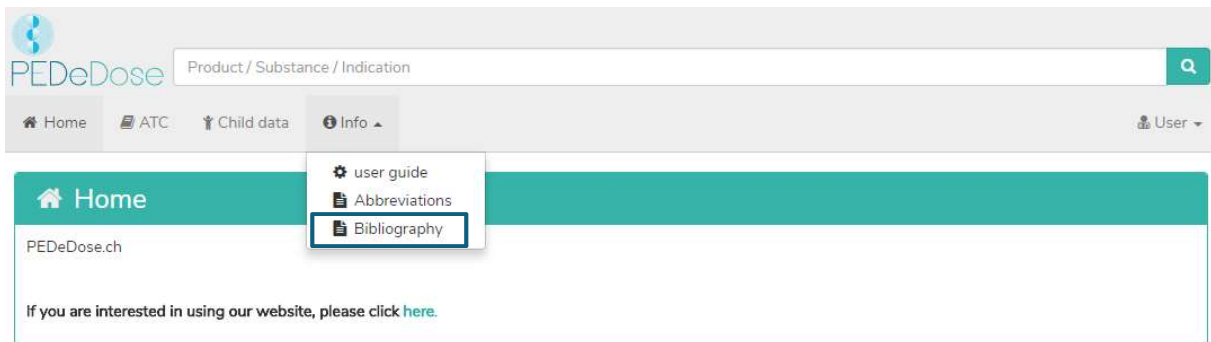
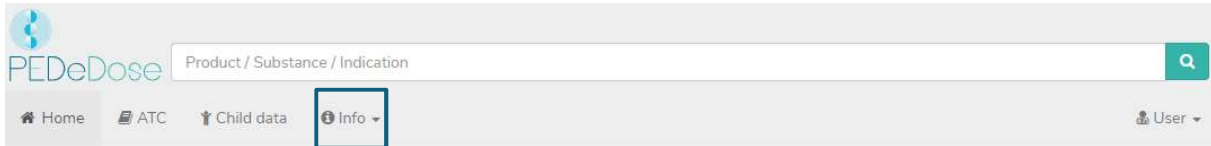
## 5.4 Abbreviations

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



## 5.5 Bibliography

Click on the “Info” button at the top of the page to open a drop-down menu. Selecting “Bibliography” opens the “Bibliography” field, which lists all references used in PEDeDose.



## 6. Complaint and Feedback Procedure

Technical and content-related errors in PEDeDose detected by the user must be reported to PEDEus as soon as possible after their detection via email ([info@pedeus.ch](mailto:info@pedeus.ch)).

## 7. Contact data


### 7.1 General

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)
- [www.kinderdosierungen.ch](http://www.kinderdosierungen.ch)

## 8. Primary label

REF SN	PEDeDose 2.0 2018	CE
	i	
	PEDeus Technoparkstrasse 1 8005 Zurich Switzerland <a href="http://www.pedeus.ch">www.pedeus.ch</a> <a href="mailto:info@pedeus.ch">info@pedeus.ch</a> <a href="http://www.pedeus.ch/">http://www.pedeus.ch/</a>	

## 9. ISS ID

Internal number for ISS (software developer) quality management system.

ISS ID: 11064