

## Instructions for use

# **PEDeDose**

Pediatric Dosages Decision Support for Healthcare Professionals

Effective date: 18/06/2018



## **Table of contents**

<b>1.</b>	General	3
1.1	Copyright	
1.2	Accessibility	3
1.3	Login	4
1.3	3.1 PEDeDose login	4
1.3	3.2 Swiss-rx-login	4
1.3	3.3 IP-address login	4
1.4	Language	4
1.5	Technical information and requirements	5
<b>2.</b>	Dosages	6
2.1	Age and weight	6
2.2	Maximum doses	7
2.3	Grade of recommendation	7
<i>3.</i>	Calculation	8
3.1	Dosage calculation	8
3.2	Child data: calculation basis	8
3.3	Calculation of preterm infant dosages	9
4.	Detailed instructions for use	9
4.1	Child data	9
4.2	Search	10
4.2	2.1 Substance search	11
4.2	2.2 Indication search	16
4.2	2.3 Product search	19
4.3	ATC	21
4.4	Abbreviations	22
4.5	Bibliography	22
<i>5.</i>	Complaint and Feedback Procedure	23
<i>6.</i>	Contact data	23
6.1	General	23
6.2	Web addresses PEDeDose software	23



#### 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 control automated clinical processes. The final decision on the medication remains with the attending healthcare professional.

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. PEDeDose is available for users in European countries. For the Swiss market, additional (not exhaustive) information (such as adverse drug reactions or application) of individual products is provided in German and French.

PEDeDose database does not claim to be exhaustive.

#### 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 / 365 days (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) 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

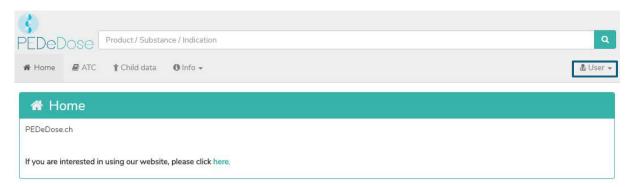
PEDeDose is available in German, French and English.

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

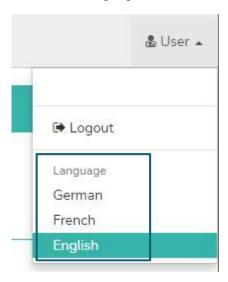




After logging in, the language can be selected by clicking on the "User" button, see below:



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 2.0 applies for PEDeDose versions 2.0.0 through 2.0.99.

Page 5 of 23 Software version: 2.0 Effective date: 18/06/2018



### 2. Dosages

There is limited availability of clinical studies regarding dosages in children. The dosages displayed were carefully reviewed based on available literature and common practice of physicians at the University Children's Hospital Zurich. For better assessment of the dosages' accuracy, grades of recommendation (A-D) are displayed right next to the dosages (see section 2.3).

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

## 2.1 Age and weight

Each dosage in PEDeDose is coupled to age and/or weight. The following table with examples explains how age and weight is to be interpreted.

Symbol/age or weight	Explanation
< x	Below age/weight x
≥ X	Above or equal age/weight x
a – b	From age/weight a (age/weight a is included) to age/weight b (age/weight b is not included)
10 D – 6 M	From 10 days to 5 months and 30/31 days
6 M – 12 Y	From 6 months and 0 days to 11 years and 364 days
≥ 12 Y	From the 12 <sup>th</sup> birthday
1 D – 28 D	From day 1 up to and including 27 days (preterm infants not included)
< 28 D	From age 0 up to and including 27 days (up to 43 6/7 weeks of postmenstrual age (PMA) for preterm infants (PI))
32 W (PMA) – 36 W (PMA)	From week 32 and 0 days of postmenstrual age up to and including 35 weeks and 6 days of postmenstrual age
≤ 50 kg	Weight under or equal to 50 kg
5 – 40 kg	From 5.00 to 39.99 kg



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

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

#### 2.2 Maximum 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
А	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)

Page **7** of **23** Software version : 2.0 Effective date: 18/06/2018



(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)
В	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
С	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
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 (weight and height). An error message 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.

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.

Page 8 of 23 Software version: 2.0 Effective date: 18/06/2018



#### 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.

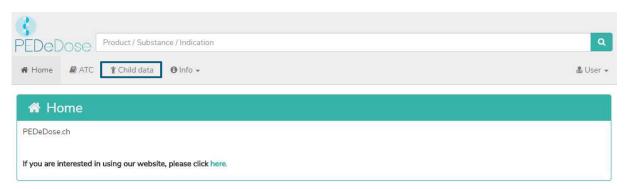
Preterm infants are born prior to the completed 37<sup>th</sup> week of pregnancy. For dosage calculation, they remain preterm infants until the postmenstrual age of week 39 and 6 days is reached. They change into neonate age for dosage calculation from gestational week 40 and 0 days. After that, the 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. Detailed instructions for use

#### 4.1 Child data

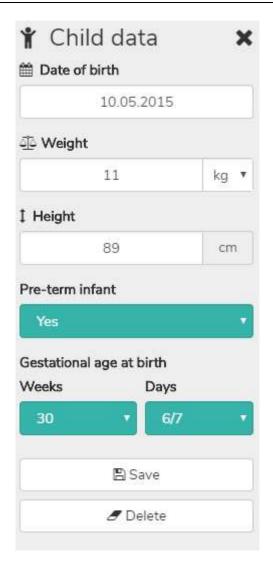
Clicking on "Child data" opens a window in which you can enter information concerning the child for which a drug dosage is to be prescribed.



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)





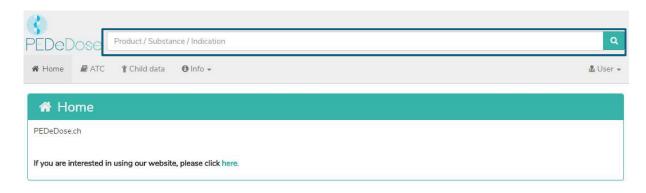
For preterm infants, select "Yes" in the field "Preterm infant". Subsequently, the gestational age at birth is entered in weeks and days (see section 3.3).

The entered data are saved by clicking on the "Save" button or deleted by clicking on the "Delete" button.

#### 4.2 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.

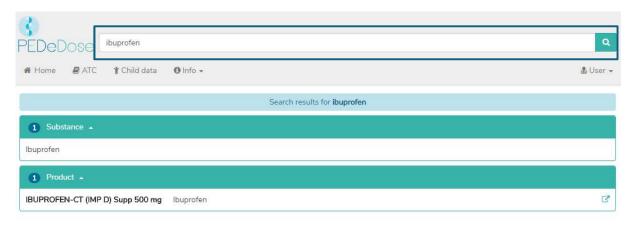




#### 4.2.1 Substance search

#### a) Substance

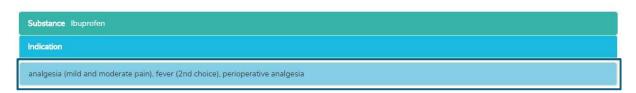
The substance name is entered in the "Search" field (e.g. ibuprofen).



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

#### b) Indication

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

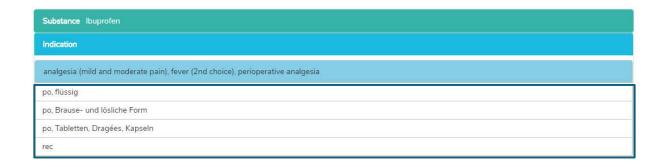


#### c) Application / route of administration

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.

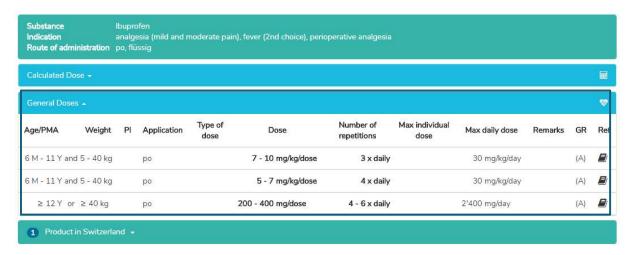
Page 11 of 23 Software version : 2.0 Effective date: 18/06/2018





#### d) General Doses

Clicking on an application (i.e. "po, flüssig") opens the "General Doses" window, see below.



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.

Page 12 of 23 Software version : 2.0 Effective date: 18/06/2018

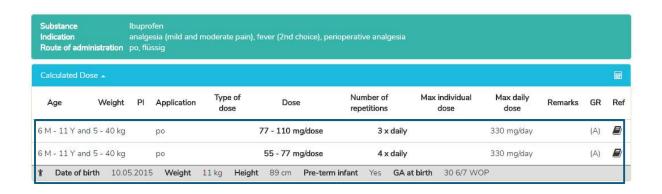


Dose	Usually in mg/kg/dose, for adults often mg/dose
Number of repetitions	Number of repetitions per day (2 x daily, 3 x daily, etc.)
Max individual dose	Maximal dose per single administration
Max daily dose	Maximal dose per day
Remarks	Remarks regarding dosage, application, etc.
GR	Grade of recommendation (see chapter 2.3)
Ref	Reference (number of reference on which the dosage is based), see "Bibliography" (chapter 4.5) for reference list

#### 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).)



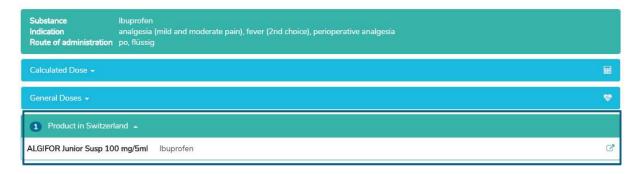


Page 13 of 23 Software version : 2.0 Effective date: 18/06/2018

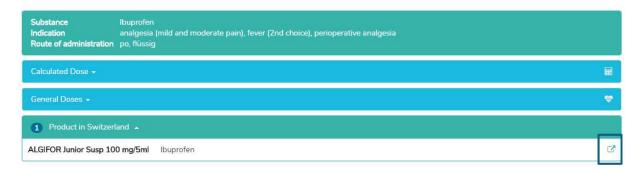


#### f) Products in Switzerland

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.



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.



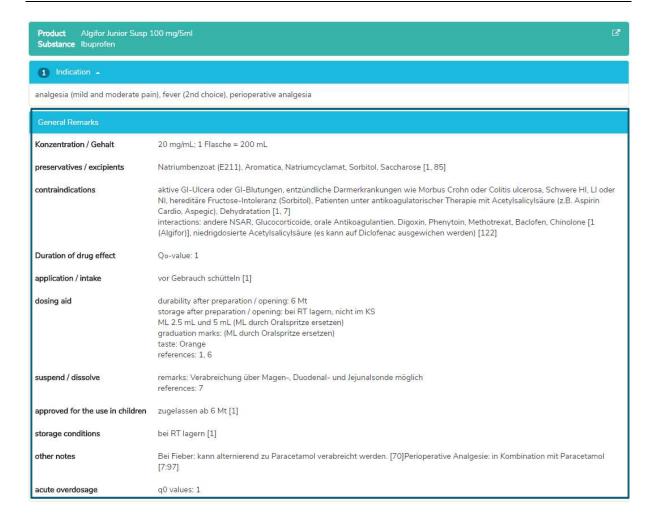
#### g) General Remarks

By clicking on the "Product in Switzerland" field (ALGIFOR Junior Susp 100 mg/5ml in the example), the "General Remarks" window opens, see below.



Page 14 of 23 Software version : 2.0 Effective date: 18/06/2018





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.

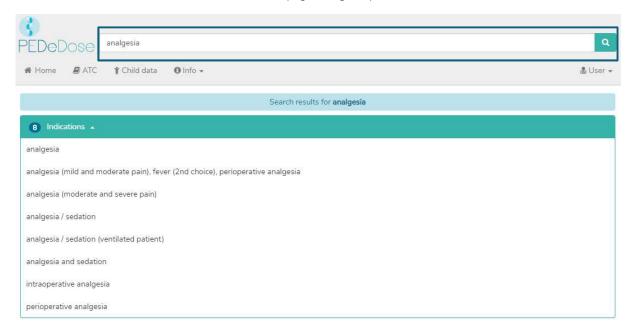
Page 15 of 23 Software version : 2.0 Effective date: 18/06/2018



#### 4.2.2 Indication search

#### a) Indication

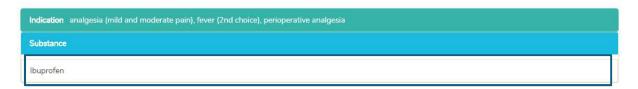
The indication is entered in the "Search" field (e.g. analgesia).



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):



#### c) Application / route of administration

Clicking on a substance (example "lbuprofen") opens the selection of the applications / route of administrations, see below.

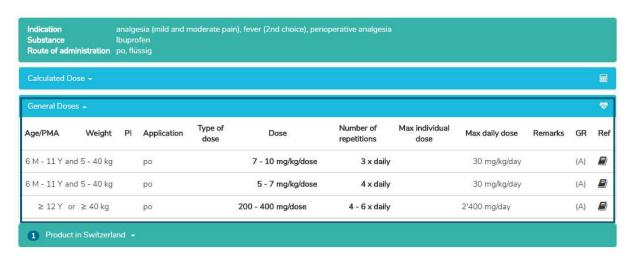
Page 16 of 23 Software version : 2.0 Effective date: 18/06/2018



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

#### d) General Doses

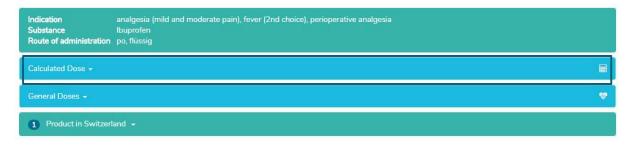
Clicking on an application (example "po, flüssig") opens the "General Doses" window, see below.



In the "General Doses" window you see the information described under point d)4.2.1.

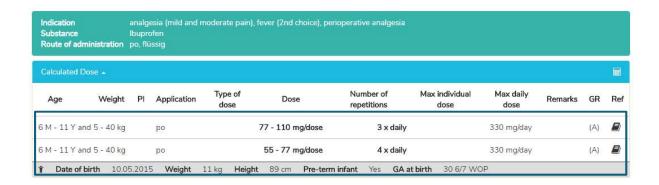
#### e) Calculated Dose

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  $4 \times \text{daily}$ ).)



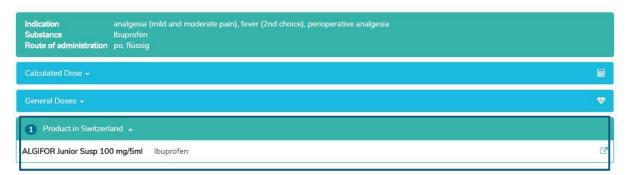
Page 17 of 23 Software version : 2.0 Effective date: 18/06/2018



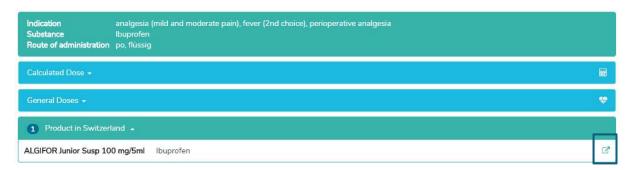


#### f) Products in Switzerland

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.



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.



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)4.2.1.

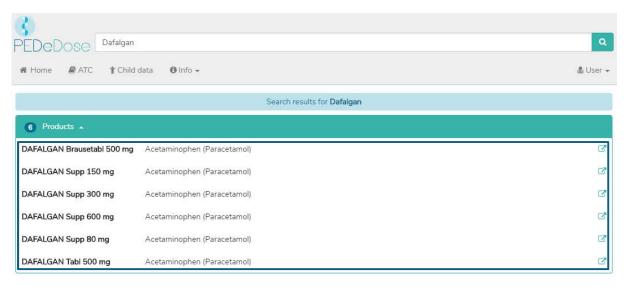


#### 4.2.3 Product search

The product search is only available for Swiss users.

#### a) Product

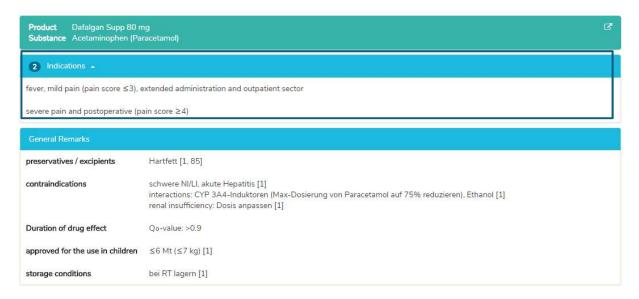
The product name is entered in the "Search field" (e.g. Dafalgan).



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):

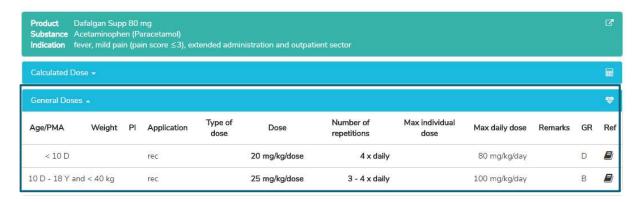




Below the indications you can find the "General remarks" regarding the selected product. In this field, additional information about the selected product is displayed (e.g. preservatives, excipients, contraindications).

#### c) General Doses

Clicking an indication (in this case "fever, mild pain (pain score ≤3), extended administration and outpatient sector") opens the window "General Doses", where all doses for the selected product are displayed, see below.

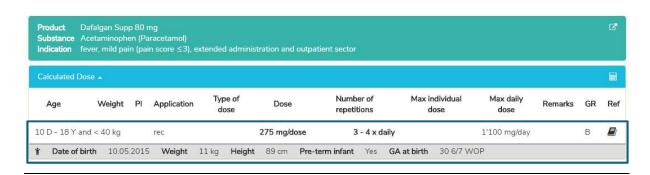


In the "General Doses" window you see the information described under point d)4.2.1.

#### 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 4.1).





Page 20 of 23 Software version : 2.0 Effective date: 18/06/2018



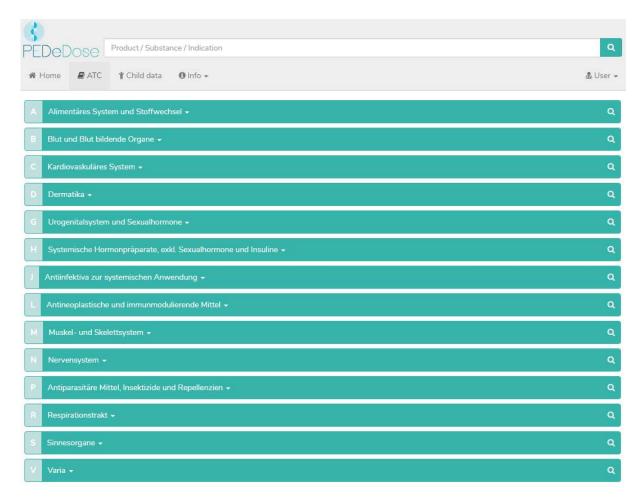
Below the section "Calculated Dose", the child data (date of birth, weight, height, preterm infant, GA (gestational age) at birth) are displayed.

In the "General Remarks" window you see the information described under point g)4.2.1.

#### 4.3 **ATC**

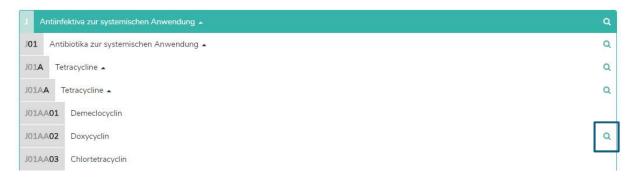
By clicking the "ATC" button at the top of the page, the ATC selection drops down, see below.





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.



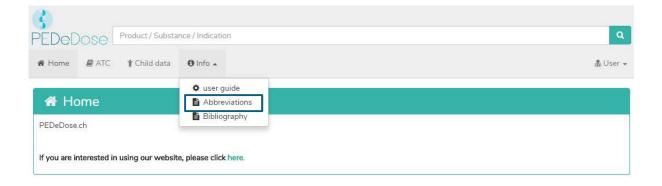


The substances not marked with a magnifying glass are not included in PEDeDose.

#### 4.4 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.





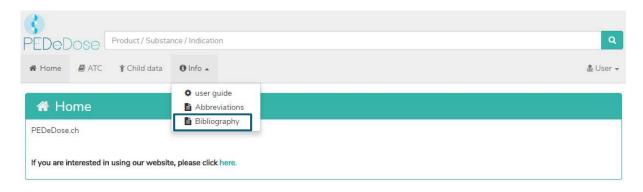
#### 4.5 Bibliography

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.



Page 22 of 23 Software version : 2.0 Effective date: 18/06/2018





## 5. 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).

#### 6. Contact data

#### 6.1 General

PEDeus AG Technoparkstrasse 1 8005 Zurich Switzerland info@pedeus.ch +41 (0)44 521 73 80

## 6.2 Web addresses PEDeDose software

- www.pededose.ch (main address)
- www.pededose.net
- www.pededose.org
- www.kinderdosierungen.ch