

Instructions for use

PEDeDose

**Clinical decision support tool for
drug dosages for healthcare professionals**

Table of contents

1 General	4
1.1 Copyright	4
1.2 Accessibility	5
1.3 Language	5
1.4 Technical information and requirements	6
1.5 Intended purpose	6
1.6 Use specification	6
1.6.1 Medical indication	6
1.6.2 Patient population	6
1.6.3 Intended user	6
a) End users	6
b) System integrators	7
c) Operators	7
1.6.4 User environment	7
1.6.5 Contraindications	7
1.6.6 Warnings, precautions and/or measures	7
1.6.7 Training	7
1.7 Residual risks	7
1.8 Clinical benefit	8
1.9 Technical performance	8
2 Dosages	8
2.1 Age and weight	9
2.2 Dosages for preterm infants and neonates	11
2.3 Repetitions / administration frequency	13
2.4 Maximum dosage	14
2.5 Grade of recommendation	15
3 Calculation	16
3.1 Dose calculation	16
3.2 Patient data: calculation basis	16
3.3 Calculation of preterm infant doses	17
3.4 Dosage adjustment in patients with kidney impairment	18
4 Web service	19

4.1	Dose check	19
5	Products	20
5.1	Products assigned to the dosage datasets	20
5.2	Product lists	21
6	Operating functions	22
6.1	Magnifying glass	22
6.2	Printing	22
7	Detailed instructions for use	22
7.1	Patient data	22
7.2	Search	25
7.2.1	Substance search	25
7.2.2	Indication search	34
7.2.3	Product search	39
7.3	Calculating the adjusted dosage in patients with kidney impairment	44
7.3.1	Display of the adjusted dosage	44
7.3.2	Display, if no adjusted dosage has been calculated	46
7.3.3	Display, when searching by active substance or indication	48
7.3.4	Display, when searching by product	48
7.4	ATC code	50
7.5	Abbreviations	51
7.6	Literature	52
8	Complaints and feedback	53
9	Contact information	54
9.1	General data	54
9.2	Web addresses PEDeDose application	54
10	Primary label	54
11	Certifications	55
12	Annexes	55

1 General

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

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

PEDeDose provides 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 for healthcare professionals. 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 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. System integrators also receive the annexes I (Web service manual PEDeDose) and II (Deep links advanced manual PEDeDose) for the integration of the web service or the deep links into primary systems.

If you require the instructions for use to be sent to you in paper form, please contact PEDeus AG (see chapter 9.1).

1.1 Copyright

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

1.2 Accessibility

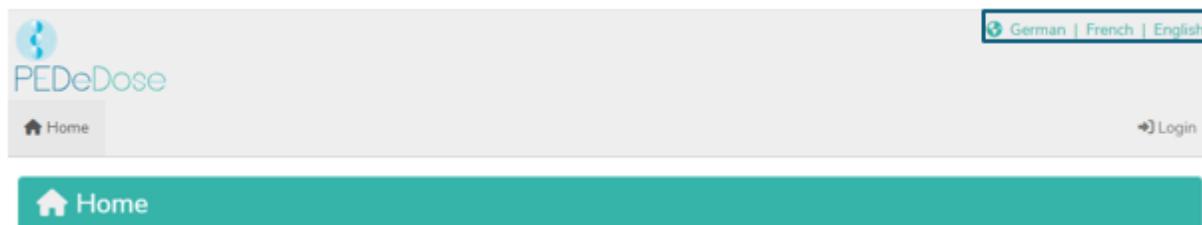
PEDeDose is intended for use by healthcare professionals. The access to the product is restricted by state-of-the-art login solutions.

Usually, PEDeDose is accessible 24 hours a day / 365 days a year, unforeseen circumstances reserved. PEDeDose can only be used by registered users. Individual users also have the option of registering via swiss rx login. At PEDeDose the login via swiss-rx-login is limited to the user type "licensed academic professionals" on the basis of the personal data according to the medical profession register of the Federal Office of Public Health (Switzerland).

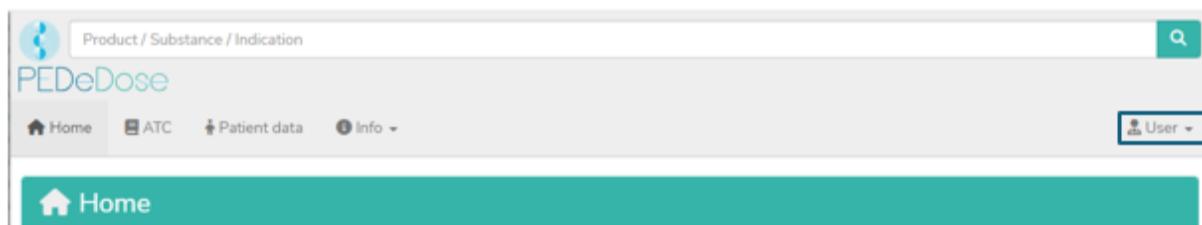
1.3 Language

PEDeDose is available in German, French and English.

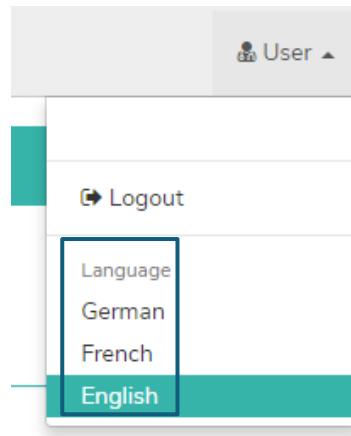
The language is selected on the top right of the home screen, see below:



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:



1.4 Technical information and requirements

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

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

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

These instructions for use apply for PEDeDose versions V3.0.X or until a newer version is published. It replaces the previous version.

1.5 Intended purpose

The product PEDeDose containing the software PEDeDose is intended to support healthcare professionals in medication by providing patient-specific dosage information based on the patient's body weight, age, body size and kidney function, if applicable. Individual dosage recommendations can be calculated by using the integrated calculator. Medication information is maintained in a data base, which is part of the software.

The software is not intended to control automated clinical processes. The final decision on the medication remains with the attending healthcare professional.

1.6 Use specification

1.6.1 Medical indication

PEDeDose provides medication information and individual dosing calculation for different indications.

1.6.2 Patient population

PEDeDose is intended to be used for patients of all age groups, including neonates (term and preterm babies), infants, toddlers, children, adolescents and adults.

No reservations are defined with respect to the medical condition of patients.

1.6.3 Intended user

a) End users

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

b) System integrators

PEDeDose is intended to be integrated by software developers into primary systems such as clinical information systems.

c) Operators

PEDeDose medication data is intended to be managed exclusively by the operators (PEDeus employees) being medical or pharmaceutical professionals.

1.6.4 Use environment

PEDeDose is intended to be used either as standalone (website) or integrated in primary systems, e.g. clinical information systems.

Intended users will have access to PEDeDose in different environments, including access from hospitals, ambulances, medical cabinets, pharmacies and at home.

1.6.5 Contraindications

Not applicable

1.6.6 Warnings, precautions and/or measures

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

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

1.6.7 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.

1.7 Residual risks

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

1.8 Clinical benefit

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

1.9 Technical performance

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

2 Dosages

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

However, those dosages do, except for impaired kidney function, not consider individual characteristics such as for example any other impaired organ function, drug interactions, obesity, underweight, hypoalbuminaemia, hyperbilirubinaemia or genetic polymorphism. Kidney function is only taken into account if the pharmacokinetic properties of the active substance are sufficiently known. 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 PEDEus is based on age and/or weight. In premature infants and neonates, dosages may also depend on postnatal age (PNA).

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

Symbol/age or weight	Explanation
$<x$	below age/weight x
$\geq x$	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
$\geq 12\text{ Y}$	from the 12 th birthday
1 D - 28 D	from day 1 up to and including 27 days (preterm infants not included)
$<28\text{ D}$	neonates (preterm infants included) up to and including 27 days
PMA 32 wk - PMA 36 wk	from 32 weeks and 0 days postmenstrual age up to and including 35 weeks and 6 days postmenstrual age
PNA $<7\text{ D}$	up to and including a postnatal age of 6 days
PNA $\geq 7\text{ D}$	from and including a postnatal age of 7 days
$<50\text{ kg}$	weight below 50 kg
5 - 40 kg	from 5.00 to 39.99 kg

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

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

2.2 Dosages for preterm infants and neonates

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

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

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

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

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

The following ages are used in connection with preterm birth:

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

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

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

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

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

2.3 Repetitions / administration frequency

Administration frequency is expressed either as number of daily repetitions or as dosing interval (in hours). 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
every 24 h	one dose every 24 h
every 6 - 8 h	one dose every 6 h to every 8 h

2.4 Maximum dosage

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

The following is an example of the explanations above:

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

If a child weighs <40 kg, the maximum single dose must not be administered, but the dosage must be calculated using the formula 'body weight in kg x dose 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 and <50 kg, the maximum single dose of 400 mg/dose is administered (40 kg \times 10 mg/kg/dose). For children weighing more than 40 kg, no calculation takes place anymore, as the maximum single dose has been reached and must not be exceeded.

The calculator in PEDEdose considers maximum dosages in the calculations.

2.5 Grade of recommendation

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

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

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

3 Calculation

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

3.1 Dose calculation

The PEDEose website allows the calculation of dosages after entering date of birth, body weight and - if necessary – height of a patient. With preterm infants, also the gestational age at birth is entered. For dosages that relate to the body surface, the body surface is estimated based on the Mosteller formula¹. A few datasets do not permit dosage calculation. In this case, a corresponding warning message is displayed.

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

3.2 Patient data: calculation basis

The following values are allowed for the weight and height (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.

Patient data entries are checked for plausibility based on percentile curves^{2,3} (weight and height). A warning is shown in case of weight and/or height below the 1st or above the 99th percentile if the patient is a child under 18 years of age. In preterm infants, a warning is shown in case of weight and/or height below the 3rd or above the 97th percentile.

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

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

¹Mosteller RD. Simplified calculation of body surface area. *N Engl J Med* 1987; 317(17): 1098.

²Braegger C et al. New Swiss growth charts. *Paediatrica* 2011; 22(1): 9-11.

³Pädiatrie Schweiz. Recommendation regarding the request to adapt the current Swiss growth charts. Oktober 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 patient data.

Preterm birth is when the child is born before 37 weeks of gestation. For dosage calculation purposes, neonates born before 37 weeks of gestation are considered preterm up to a postmenstrual age (PMA) of 39 weeks and 6 days. From a postmenstrual age (PMA) of 40 weeks and 0 days, the corrected age is used if gestational age and prematurity are recorded. The calculation according to corrected age (corrA) is maintained until the end of the 36th month (chronological age (chronA)), then the dosage is calculated based on chronological age.

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

Here are some examples:

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

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

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

Substance	Acetaminophen (Paracetamol) 										
Indication	analgesia (mild pain, pain score ≤3), fever 										
Route of administration	PO, liquid										
Calculated dose 											
Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref
3 D	2800 g	PO			28 - 42 mg/dose	3 - 4 x daily		168 mg/day	D 		
⌚ Date of birth	04.11.2024	Weight	2800 g	PI	Yes	GA 35 3/7 WOP	corrA 3 D	PMA 40 3/7 wk	PNA 5 wk		

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

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

3.4 Dosage adjustment in patients with kidney impairment

For patients with impaired kidney function, the dosage can be adjusted depending on the patient's kidney function and the extra-renal elimination fraction (Q_0 value) of the active substance. Depending on the active substance, the adjustment is made by either reducing the dose or extending the dosing interval. However, this function is not available for all active substances.

To adjust the dosage for kidney impairment, also the sex must be entered with the patient data, a laboratory parameter selected, and its value entered. Available laboratory parameters are serum creatinine [$\mu\text{mol/L}$], cystatin C [mg/L] and the glomerular filtration rate (GFR) [mL/min/1.73m^2]. As there are, in addition to the serum creatinine and cystatin C value, other, less frequently used methods for estimating or directly measuring GFR, PEDEdose also offers the option of entering GFR directly.

The laboratory parameters entered are checked for plausibility. A warning is displayed if the entered value is below or above a certain threshold value. As GFR can fluctuate greatly in certain cases, it is important to always ensure that a current measured value is entered.

Using published empirical formulae,^{4,5,6,7} the estimated glomerular filtration rate (eGFR), which is an indicator of kidney function, is then calculated based on the laboratory parameter entered. Using serum creatinine, the eGFR can be calculated from an age of 7 days for term infants or a corrected age of 28 days for former preterm infants. In the first few days after birth, GFR is still so variable that adjusting the dosage based on GFR is too uncertain. Cystatin C can be used to calculate the eGFR from the age of 1 year.

%eGFR is then calculated as a percentage of the normal GFR (reference value in healthy people). For children <1 year of age, different GFR reference values are used to calculate the percentage eGFR

⁴Smeets NJL et al. Maturation of GFR in term-born neonates: An individual participant data meta-analysis. *JASN* 2022; 33(7): 1277-1292.

⁵Pierce CB et al.. Age- and sex-dependent clinical equations to estimate glomerular filtration rates in children and young adults with chronic kidney disease. *Kidney Int* 2021; 99(4): 948-956.

⁶CKD-EPI creatinine equation (2021). National Kidney Foundation. <https://www.kidney.org/content/ckd-epi-creatinine-equation-2021>. Online access 04/2024.

⁷CKD-EPI cystatin C equation (2012). National Kidney Foundation. <https://www.kidney.org/content/ckd-epi-cystatin-c-equation-2012>. Online access 04/2024.

depending on age⁸. For patients ≥ 1 year of age, a GFR of $120 \text{ mL/min}/1.73\text{m}^2$ is assumed to be 100%. The Dettli formula⁹ is then used to calculate the individual elimination capacity (Q) for the selected active substance, which then serves as the basis for adjusting the dosage. If Q is less than or equal to 0.8 and %eGFR is between 8 and 75%, the dosage is adjusted accordingly. An exception are e.g. single and loading doses, which are not adjusted.

For active substances that are nephrotoxic or contraindicated below a certain GFR threshold, a corresponding note is displayed with the calculation. For further information, see chapter 7.3.

4 Web service

This part of the instructions for use is for users of the web service. The web service provides access to PEDEose 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 patient data. All alerts and warnings provided by PEDEose must be displayed to the user in the clinical information system, in a medical practice or pharmacy software.

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

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, or the maximal single or daily dose (if available) is exceeded, the user receives a warning together with the deviation of the dosage in percent, see table below.

⁸Rhodin MM et al. Human renal function maturation: a quantitative description using weight and postmenstrual age. *Pediatr Nephrol* 2009; 24(1): 67-76.

⁹Dettli L. The kidney in pre-clinical and clinical pharmacokinetics. *Jpn J Clin Pharmacol Ther* 1984; 15(1): 241-254.

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 specifies a dosage as a range, the highest (for upper limits) or the lowest value (for lower limits) is used for the tolerance calculation, respectively.

The dose check is not designed to detect over- or underdosages when several identical or similar active substances are being prescribed to a patient. In the case of dosages that have to be up-titrated (e.g. anti-epileptic drugs) or active substances whose tolerance is very individual (e.g. morphine), an OK in the dose check may give a false sense of security and must therefore be interpreted individually.

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

5 Products

5.1 Products assigned to the dosage datasets

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

- **Excipients:** The excipients in a product are checked. If a product contains unsuitable excipients, this is noted under the «Product specific remarks», including the age up to which the excipient in question is unsuitable.
- **Approval according to product information:** If possible, products are linked that are approved for the indication and the age of the corresponding dosage dataset. If no approved products are available, off-label links are made, always taking into account further criteria such as excipients, contraindications, etc.

- **Dosage strength:** Usually, products are assigned to the dosage datasets which, with regard to their dosage, are in a range covering half of the lowest dosage to twice of the highest dosage. In the case of solid oral products, divisibility and crushability are taken into account for 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 PEDEuse. For this purpose, the institution will send PEDEus a list of products to be labelled by individual arrangement. These products will be marked with a star in the respective institution after processing by PEDEus. This may be used for example to display the institution's internal products or favourites in PEDEuse (see figure below for products with ibuprofen, oral, liquid: One product is marked with a star).

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	
Substance	
Ibuprofen ★	
Products	

6 Operating functions

6.1 Magnifying glass

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



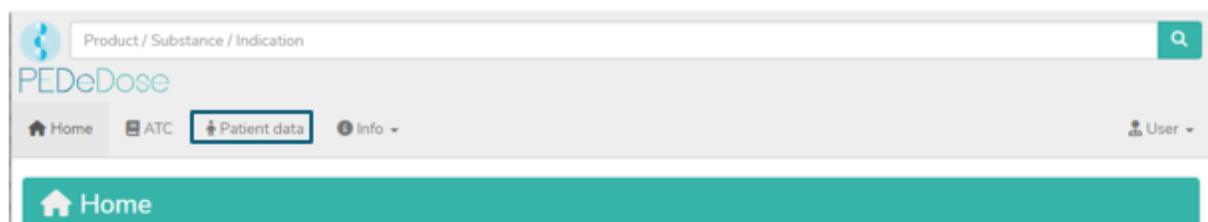
6.2 Printing

If required, an extract can be printed from PEDEose 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 Patient data

Clicking on «Patient data» opens a window in which you can enter information concerning the patient 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 for which the body surface is necessary for dose calculation, for patients for which the dosage needs adjustment due to kidney impairment or as a prerequisite for the calculation of the BMI)
- Preterm infant (yes or no)
- Gestational age at birth ([«Weeks» and «Days»], only after selecting «Yes» for Preterm infant)

Patient data

Date of birth*
09.12.2024

Weight*
6 kg

Height
65 cm

Preterm infant
Yes

Gestational age at birth
Weeks* Days*
30 6/7

Kidney impairment
No

Always confirm patient data before calculation

Save

Delete

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

- Kidney impairment (yes or no)
- Sex (male or female)
- Laboratory parameter (serum creatinine [$\mu\text{mol/L}$], cystatin C [mg/L] or GFR [mL/min/1.73 m^2]; only shown after selecting «Yes» for Kidney impairment)

Patient data

Date of birth*
09.12.2022

Weight*
12 kg

Height
85 cm

Preterm infant
No

Kidney impairment
Yes

Laboratory parameter*
Cystatin C

Value*
1.1 mg/L

Sex*
 Male Female

Always confirm patient data before calculation

Save

Delete

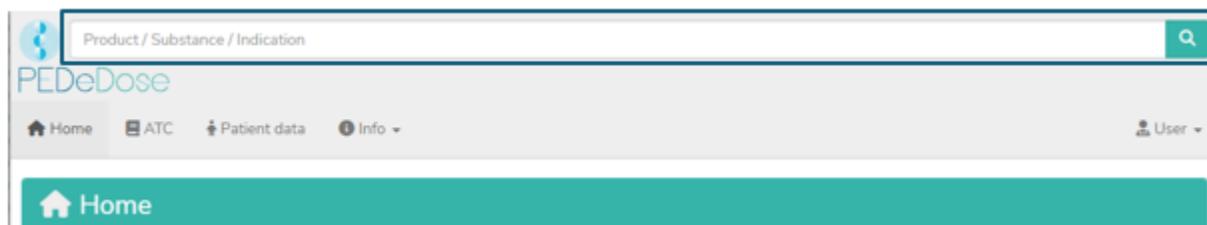
If «Yes» is selected in the «Kidney impairment» field, subsequently the sex must be entered, the laboratory parameter selected, and its value entered (see chapter 3.4).

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

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

7.2 Search

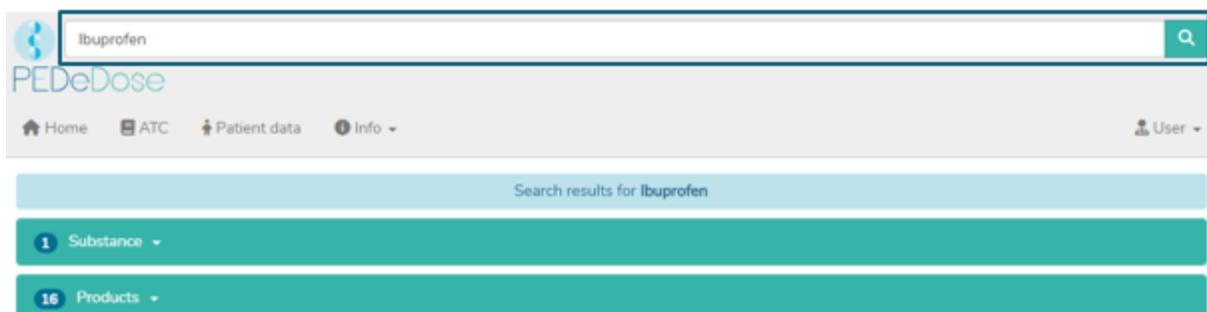
In the «Search» field, either a substance name, a drug indication or a product name can be entered; at least three letters or two letters (characters) and «%» must be entered. The search function is not case-sensitive.



7.2.1 Substance search

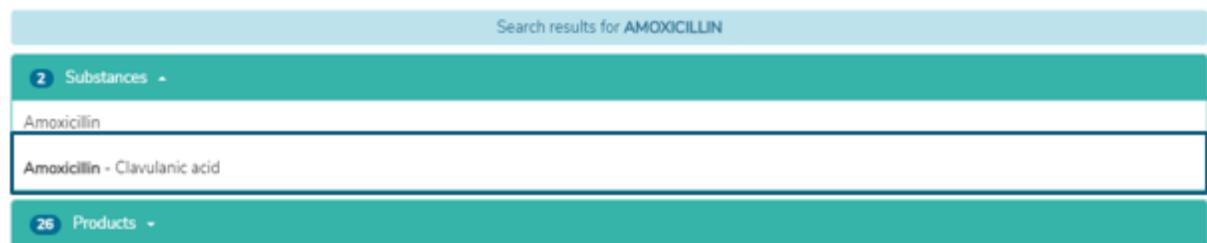
7.2.1.1 Substance

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



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

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



7.2.1.2 Indication

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

Substance Ibuprofen **Indications**

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

patent ductus arteriosus (PDA)

7.2.1.3 Application

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

Substance Ibuprofen **Indications**

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

PO, liquid

PO, effervescent and liquid forms

PO, tablets, dragees, capsules

REC

patent ductus arteriosus (PDA)

7.2.1.4 General doses

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

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

Substance	ibuprofen	Q									
Indication	analgesia (mild / moderate pain), fever, perioperative analgesia	Q									
Route of administration	PO, liquid										
Calculated dose											
General doses + 											
Age/PMA	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref
3 mth - 6 mth and \geq 5 kg			PO		7.5 - 10 mg/kg/dose	3 x daily			B		
3 mth - 6 mth and \geq 5 kg			PO		5 - 7.5 mg/kg/dose	4 x daily			B		
6 mth - 18 Y and 5 - 40 kg			PO		7.5 - 10 mg/kg/dose	3 x daily			(A)		
6 mth - 18 Y and 5 - 40 kg			PO		5 - 7.5 mg/kg/dose	4 x daily			(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			A		
Substance specific remarks											
attention	A good hydration of the patient is important. [185]										
renal insufficiency	creatinine clearance <30 mL/min/1.73 m ² (or $<25\%$ of the norm in infants <12 mth): do not use; creatinine clearance ≥ 30 mL/min/1.73 m ² (or $\geq 25\%$ of the norm in infants <12 mth): no dose adjustment; creatinine clearance 30-60 mL/min/1.73 m ² (or 25-50% of the norm in infants <12 mth): monitoring of renal function recommended, do not use in patients at risk of worsening renal insufficiency [58 (03/2023), 152 (Algifor, 03/2023), 338]										
Q _s value	1 [58 (03/2023)]										
contraindications	among others active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, severe HI (cirrhosis and ascites), severe RI (creatinine clearance <30 mL/min/1.73 m ² or $<25\%$ of the norm in infants <12 mth) [152 (Algifor, 03/2023)]										
interactions	among others other NSAID (including low-dose acetylsalicylic acid), glucocorticoids, oral anticoagulants, digoxin, phenytoin, quinolones, methotrexate [152 (Algifor, 03/2023)]										
12 Products in Switzerland + 											

The «General doses» window provides the following information:

Information	Explanation
Age/PMA	Age of the patient for whom the dosage is recommended (PMA: postmenstrual age, in case of a dosage for a preterm infant)
Weight	Weight of the patient for whom the dosage is recommended
PNA	Postnatal age (only relevant for neonates and preterm infants)
Application	Route of administration (REC, PO, IV, IM, etc.)
Type of dose	Loading dose, maintenance dose, etc.
Dose	Usually in mg/kg/dose, for adults often mg/dose
Number of repetitions	Number of repetitions per day (2 x daily, 3 x daily, etc.) or dosing interval (in hours)
Max single dose	Maximal dose per single administration
Max daily dose	Maximal dose per day
Remarks	Remarks regarding dosage, application, etc.
GR	Grade of recommendation (see chapter 2.5)
Ref	Reference (number of reference on which the dosage is based), see «Literature» (chapter 7.6) for the reference list. The «book symbol» works as a mouse-over button (does not work on tablets and smartphones. In these cases, the references are directly accessible).

7.2.1.5 Calculated dose

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

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

Below the section «Calculated dose», the grey bar shows the following data of the patient: «Date of birth», «Weight», «Height», «BMI», body surface area («BSA»), Premature infant («PI») and chronological age («chronA»). For premature infants, instead of the chronological age, the gestational age at birth («GA») as well as the postmenstrual age («PMA») and the postnatal age («PNA») or the corrected age («corrA») are displayed. For former preterm infants with a PMA between 40 and 44 weeks, both the corrected and the postmenstrual age are displayed. (For premature infants, see also chapter 3.3.)

Substance	Ibuprofen 												
Indication	analgesia (mild / moderate pain), fever, perioperative analgesia 												
Route of administration	PO, liquid												
Calculated dose 													
General doses 													
Substance	Ibuprofen 												
Indication	analgesia (mild / moderate pain), fever, perioperative analgesia 												
Route of administration	PO, liquid												
Calculated dose 													
Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref		
3 Y 5 mth	12 kg		PO		90 - 120 mg/dose	3 x daily			(A) 				
3 Y 5 mth	12 kg		PO		60 - 90 mg/dose	4 x daily			(A) 				
• Date of birth	11.06.2021	Weight	12 kg	Height	92 cm	BSA	0.55 m ²	BMI	14	PI	No	chronA	3 Y 5 mth

7.2.1.6 Products in Switzerland

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

General doses
▼
Heart

Substance specific remarks

attention	A good hydration of the patient is important. [185]
renal insufficiency	creatinine clearance <30 mL/min/1.73 m ² (or <25% of the norm in infants <12 mth): do not use; creatinine clearance ≥30 mL/min/1.73 m ² (or ≥25% of the norm in infants <12 mth): no dose adjustment; creatinine clearance 30-60 mL/min/1.73 m ² (or 25-50% of the norm in infants <12 mth): monitoring of renal function recommended, do not use in patients at risk of worsening renal insufficiency [58 (03/2023), 152 (Algifor, 03/2023), 338]
Q _e value	1 [58 (03/2023)]
contraindications	among others active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, severe HI (cirrhosis and ascites), severe RI (creatinine clearance <30 mL/min/1.73 m ² or <25% of the norm in infants <12 mth) [152 (Algifor, 03/2023)]
interactions	among others other NSAID (including low-dose acetylsalicylic acid), glucocorticoids, oral anticoagulants, digoxin, phenytoin, quinolones, methotrexate [152 (Algifor, 03/2023)]

12 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 100 mg/5ml mit Dosierspr	Ibuprofen	🔗
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen	🔗
IRFEN Junior Susp 100 mg/5ml	Ibuprofen	🔗
NUROFEN Dolo Junior Susp 100 mg/5ml Erdbeer	Ibuprofen	🔗
NUROFEN Dolo Junior Susp 100 mg/5ml Orange	Ibuprofen	🔗
NUROFEN Junior forte Susp 200 mg/5ml Erdbe	Ibuprofen	🔗
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen	🔗
OPTIFEN Junior Susp 100 mg/5ml	Ibuprofen	🔗

By clicking on the symbol on the right in the field «Products in Switzerland» the short information of HCI Solutions AG is opened in www.compendium.ch 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.

12 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 100 mg/5ml mit Dosierspr	Ibuprofen
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen
IRFEN Junior Susp 100 mg/5ml	Ibuprofen
NUROFEN Dolo Junior Susp 100 mg/5ml Erdbeer	Ibuprofen
NUROFEN Dolo Junior Susp 100 mg/5ml Orange	Ibuprofen
NUROFEN Junior forte Susp 200 mg/5ml Erdbe	Ibuprofen
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen
OPTIFEN Junior Susp 100 mg/5ml	Ibuprofen

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

7.2.1.7 Product specific remarks

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

11 Products in Switzerland ▾

ALGIFOR Dolo forte Susp 200 mg/5ml	Ibuprofen	
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 100 mg/5ml mit Dosierspr	Ibuprofen	
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen	
IRFEN Junior Susp 100 mg/5ml	Ibuprofen	
NUROFEN Dolo Junior Susp 100 mg/5ml Orange	Ibuprofen	
NUROFEN Junior forte Susp 200 mg/5ml Erdb	Ibuprofen	
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen	
OPTIFEN Junior Susp 100 mg/5ml	Ibuprofen	

Produkt ALGIFOR Junior 100 mg/5ml mit Dosierspr
Wirkstoff Ibuprofen

2 Indikationen ▾

Analgesie (leichte / mittelstarke Schmerzen), Fieber, perioperative Analgesie
Juvenile idiopathische Arthritis

Produkt spezifische Bemerkungen

Konzentration / Gehalt	100 mg/5 mL = 20 mg/mL; 1 Flasche = 200 mL
Eigenschaften Produkt	Konservierungsmittel / Hilfsstoffe: Saccharose (2.5 g/5 mL), Sorbitol, Xanthan, Ethanol (16.8 mg/5 mL), Natriumcyclamat, Polysorbat 80, Citronensäure-1-Wasser, Orangen Aroma, Natriumedetat, Natriumbenzoat (E211), gereinigtes Wasser (pro 5 mL <1 mmol Natrium) [152 (05/2022)] Geschmack: Orange [152 (05/2022)]
Applikation	Handling: vor Gebrauch gut schütteln [152 (05/2022)] Dosierhilfe: Dosierspritzte 5 mL mit Graduierung in 0.5-mL-Schritten [85 (11/2023)] Sonde: Verabreichung über Magen-, Duodenal- und Jejunalsonde möglich (kein spezifisches Absorptionsfenster bekannt, Resorption grösstenteils im Dünndarm) [7, 152 (05/2022), 158]
Haltbarkeit	Haltbarkeit nach Anbruch: 6 Mt bei RT [6 (03/2022)]
Zulassung bei Kindern	Schmerzen / Fieber: ≥6 Mt und ≥5 kg, Juvenile Arthritis: ≥2 J [152 (03/2023)]
Lagerbedingungen	bei RT lagern [152 (05/2022)]

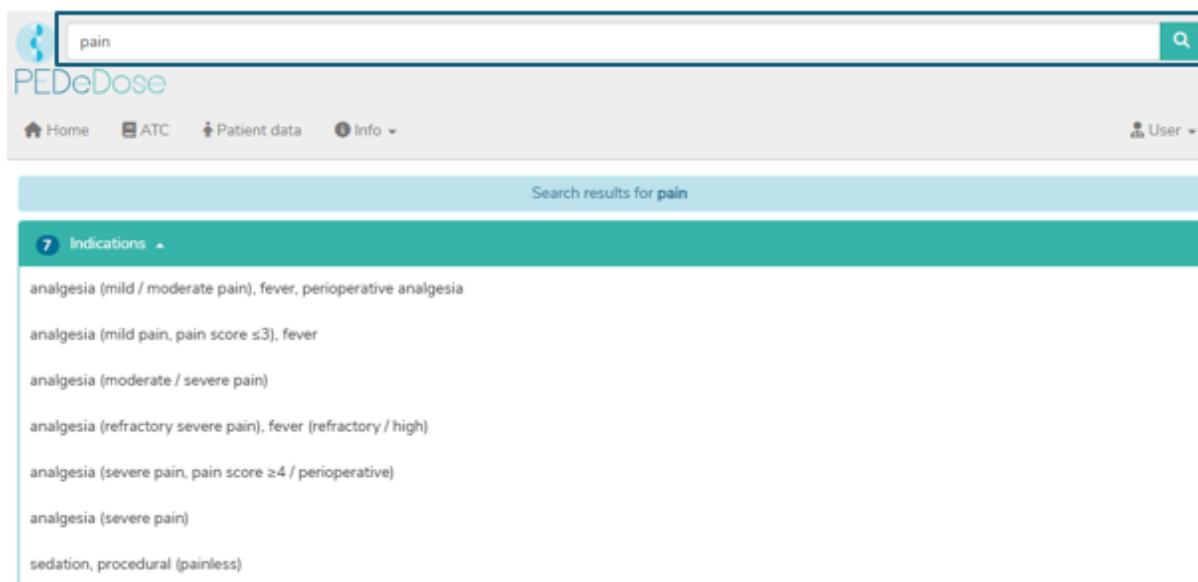
In the «Product specific remarks» window you can find information about the selected product, for instance «concentration/content», «preservatives/excipients», «dosing aids», «enteral feeding tube», «storage conditions». «Product specific remarks» of a product can be either «on label» or «off label».

When assessing whether it is an «on label» or an «off label use», users must consult the product information for healthcare professionals. There aren't «Product specific remarks» for all products.

7.2.2 Indication search

7.2.2.1 Indication

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

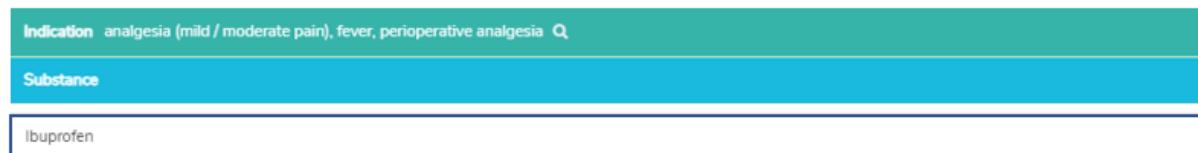


The screenshot shows the PEDEdose web interface. At the top, there is a search bar with the word "pain" typed into it. Below the search bar is the PEDEdose logo and a navigation bar with links for "Home", "ATC", "Patient data", "Info", and "User". The main content area has a header "Search results for pain". Below this, a section titled "7 Indications" is shown, containing a list of seven items: "analgesia (mild / moderate pain), fever, perioperative analgesia", "analgesia (mild pain, pain score ≤3), fever", "analgesia (moderate / severe pain)", "analgesia (refractory severe pain), fever (refractory / high)", "analgesia (severe pain, pain score ≥4 / perioperative)", "analgesia (severe pain)", and "sedation, procedural (painless)".

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

7.2.2.2 Substance

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



The screenshot shows the PEDEdose interface with a "Substance" field. The field contains the word "Ibuprofen". Above the "Substance" field, there is a "Indication" field containing the text "analgesia (mild / moderate pain), fever, perioperative analgesia".

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

7.2.2.3 Application

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

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

7.2.2.4 General doses

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

Substance	Ibuprofen										
Indication	analgesia (mild / moderate pain), fever, perioperative analgesia										
Route of administration	PO, liquid										
Calculated dose											
General doses											
Age/PMA	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref
3 mth - 6 mth and ≥5 kg			PO		7.5 - 10 mg/kg/dose	3 x daily			B		
3 mth - 6 mth and ≥5 kg			PO		5 - 7.5 mg/kg/dose	4 x daily			B		
6 mth - 18 Y and 5 - 40 kg			PO		7.5 - 10 mg/kg/dose	3 x daily			(A)		
6 mth - 18 Y and 5 - 40 kg			PO		5 - 7.5 mg/kg/dose	4 x daily			(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			A		
Substance specific remarks											
attention	A good hydration of the patient is important. [185]										
renal insufficiency	creatinine clearance <30 mL/min/1.73 m ² (or <25% of the norm in infants <12 mth): do not use; creatinine clearance ≥30 mL/min/1.73 m ² (or ≥25% of the norm in infants <12 mth): no dose adjustment; creatinine clearance 30-60 mL/min/1.73 m ² (or 25-50% of the norm in infants <12 mth): monitoring of renal function recommended, do not use in patients at risk of worsening renal insufficiency [58 (03/2023), 152 (Algifor, 03/2023), 338]										
Q ₀ value	1 [58 (03/2023)]										
contraindications	among others active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, severe HI (cirrhosis and ascites), severe RI (creatinine clearance <30 mL/min/1.73 m ² or <25% of the norm in infants <12 mth) [152 (Algifor, 03/2023)]										
interactions	among others other NSAID (including low-dose acetylsalicylic acid), glucocorticoids, oral anticoagulants, digoxin, phenytoin, quinolones, methotrexate [152 (Algifor, 03/2023)]										
12 Products in Switzerland											

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

7.2.2.5 Calculated dose

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

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

Below the section «Calculated dose», the grey bar shows the following data of the patient: «Date of birth», «Weight», «Height», «BMI», body surface area («BSA»), premature infant («PI») and chronological age («chronA»). For premature infants, instead of the chronological age, the gestational age at birth («GA») as well as the postmenstrual age («PMA») and the postnatal age («PNA») or the corrected age («corrA») are displayed. For former preterm infants with a PMA between 40 and 44 weeks, both the corrected and the postmenstrual age are displayed. (For preterm infants, see also chapter 3.3.)

Indication	analgesia (mild / moderate pain), fever, perioperative analgesia	Q											
Substance	Ibuprofen	Q											
Route of administration	PO, liquid												
Calculated dose ▾													
General doses ▾													
Substance	Ibuprofen	Q											
Indication	analgesia (mild / moderate pain), fever, perioperative analgesia	Q											
Route of administration	PO, liquid												
Calculated dose ▾													
Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref		
3 Y 5 mth	12 kg		PO		90 - 120 mg/dose	3 x daily			(A)				
3 Y 5 mth	12 kg		PO		60 - 90 mg/dose	4 x daily			(A)				
⌚ Date of birth	09.07.2021	Weight	12 kg	Height	92 cm	BSA	0.55 m ²	BMI	14	PI	No	chronA	3 Y 5 mth

7.2.2.6 Products in Switzerland

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

General doses ▾	
Substance specific remarks	
attention	A good hydration of the patient is important. [185]
renal insufficiency	creatinine clearance <30 mL/min/1.73 m ² (or <25% of the norm in infants <12 mth): do not use; creatinine clearance ≥30 mL/min/1.73 m ² (or ≥25% of the norm in infants <12 mth): no dose adjustment; creatinine clearance 30-60 mL/min/1.73 m ² (or 25-50% of the norm in infants <12 mth): monitoring of renal function recommended, do not use in patients at risk of worsening renal insufficiency [58 (03/2023), 152 (Algifor, 03/2023), 338]
Q _e value	1 [58 (03/2023)]
contraindications	among others active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, severe HI (cirrhosis and ascites), severe RI (creatinine clearance <30 mL/min/1.73 m ² or <25% of the norm in infants <12 mth) [152 (Algifor, 03/2023)]
interactions	among others other NSAID (including low-dose acetylsalicylic acid), glucocorticoids, oral anticoagulants, digoxin, phenytoin, quinolones, methotrexate [152 (Algifor, 03/2023)]

12 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 100 mg/5ml mit Dosierspr	Ibuprofen
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen
IRFEN Junior Susp 100 mg/5ml	Ibuprofen
NUROFEN Dolo Junior Susp 100 mg/5ml Erdbeer	Ibuprofen
NUROFEN Dolo Junior Susp 100 mg/5ml Orange	Ibuprofen
NUROFEN Junior forte Susp 200 mg/5ml Erdbe	Ibuprofen
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen
OPTIFEN Junior Susp 100 mg/5ml	Ibuprofen

By clicking on the symbol on the right in the field «Products in Switzerland» the short information of HCI Solutions AG is opened in www.compendium.ch 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.

11 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 100 mg/5ml mit Dosierspr	Ibuprofen
IRFEN DOLO Junior Susp 100 mg/5ml	Ibuprofen
IRFEN Junior Susp 100 mg/5ml	Ibuprofen
NUROFEN Dolo Junior Susp 100 mg/5ml Orange	Ibuprofen
NUROFEN Junior forte Susp 200 mg/5ml Erd	Ibuprofen
OPTIFEN Dolo Junior Susp 100 mg/5ml	Ibuprofen
OPTIFEN Junior Susp 100 mg/5ml	Ibuprofen

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

8 Products in Switzerland matching the data set of the calculated dose

Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref
5 mth	8 kg		PO		60 - 80 mg/dose	3 x daily			B		
5 mth	8 kg		PO		40 - 60 mg/dose	4 x daily			B		
↓ Date of birth 09.08.2024 Weight 8 kg Height 60 cm BSA 0.37 m ² BMI 22 PI No chronA 5 mth											
8 Products in Switzerland matching the data set of the calculated dose											
General doses											
Substance specific remarks											
attention	A good hydration of the patient is important. [185]										
renal insufficiency	creatinine clearance <30 mL/min/1.73 m ² (or <25% of the norm in infants <12 mth): do not use; creatinine clearance ≥30 mL/min/1.73 m ² (or ≥25% of the norm in infants <12 mth): no dose adjustment; creatinine clearance 30-60 mL/min/1.73 m ² (or 25-50% of the norm in infants <12 mth): monitoring of renal function recommended, do not use in patients at risk of worsening renal insufficiency [58 (03/2023), 152 (Algifor, 03/2023), 338]										
Q _e value	1 [58 (03/2023)]										
contraindications	among others active GI ulcers or GI bleeding, inflammatory bowel diseases such as Crohn's disease or ulcerative colitis, severe HF, severe HI (cirrhosis and ascites), severe RI (creatinine clearance <30 mL/min/1.73 m ² or <25% of the norm in infants <12 mth) [152 (Algifor, 03/2023)]										
interactions	among others other NSAID (including low-dose acetylsalicylic acid), glucocorticoids, oral anticoagulants, digoxin, phenytoin, quinolones, methotrexate [152 (Algifor, 03/2023)]										
12 Products in Switzerland											

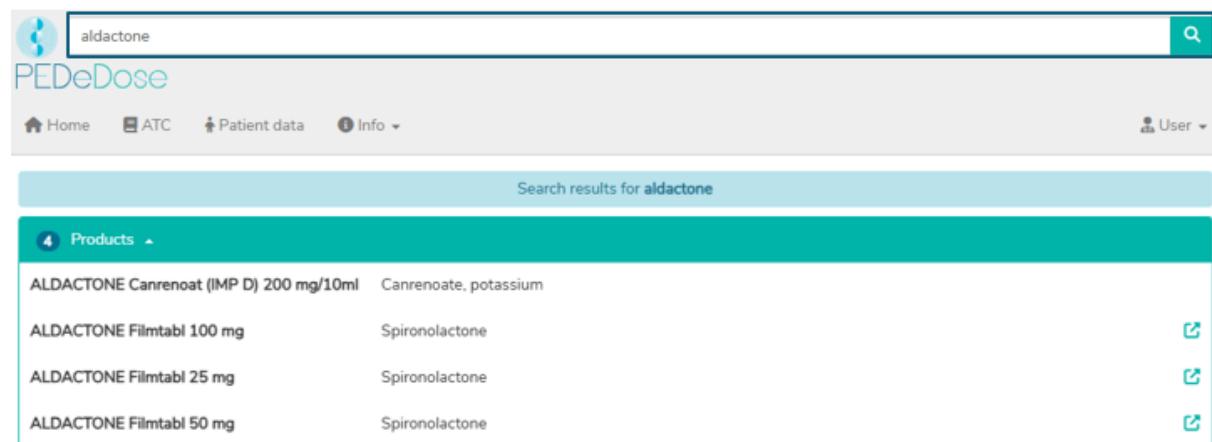
By clicking on the «Products in Switzerland» field and a product, the «Product specific remarks» window opens, see chapter 7.2.1.7.

7.2.3 Product search

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

7.2.3.1 Product

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



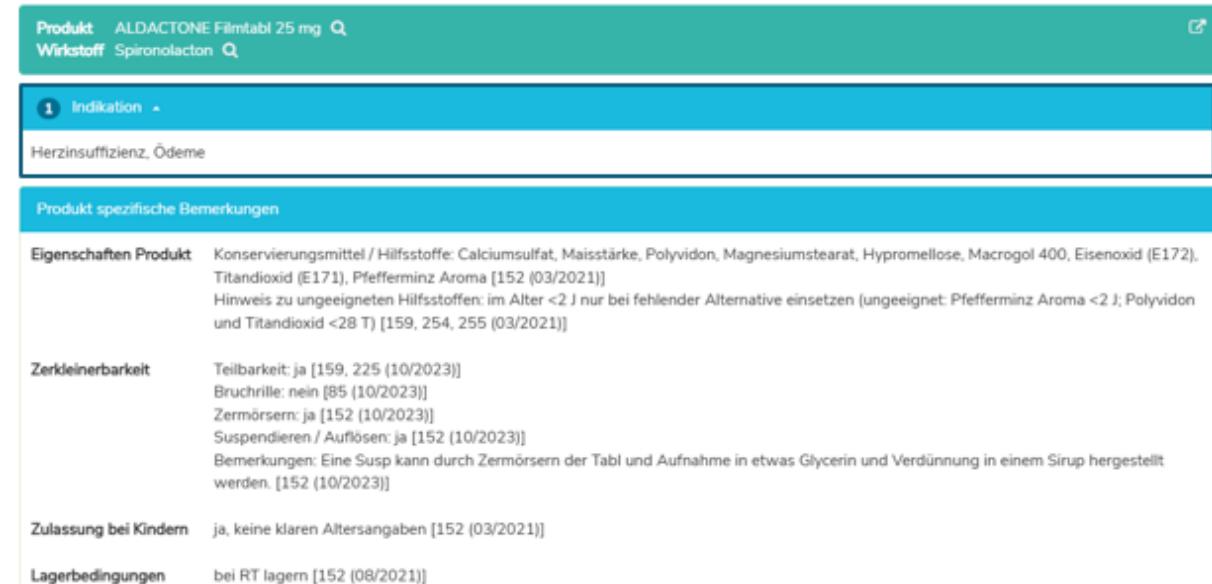
The screenshot shows the PEDEdose interface with a search bar containing 'aldactone'. Below the search bar, there are navigation links: Home, ATC, Patient data, Info, and User. The main content area is titled 'Search results for aldactone' and shows a list of products. The list includes:

Product	Active Substance	Actions
ALDACTONE Canrenoat (IMP D) 200 mg/10ml	Canrenoate, potassium	
ALDACTONE Filmtabl 100 mg	Spironolactone	
ALDACTONE Filmtabl 25 mg	Spironolactone	
ALDACTONE Filmtabl 50 mg	Spironolactone	

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

7.2.3.2 Indication

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



The screenshot shows the product details for ALDACTONE Filmtabl 25 mg. At the top, it lists the product (ALDACTONE Filmtabl 25 mg) and its active substance (Spironolacton). Below this, the 'Indikation' (Indication) section is expanded, showing 'Herzinsuffizienz, Ödeme' (Heart failure, edema). The 'Produkt spezifische Bemerkungen' (Product-specific remarks) section is also visible, containing detailed information about the product's properties, divisibility, storage conditions, and use in children.

Eigenschaften Produkt	Wert
Eigenschaften Produkt	Konservierungsmittel / Hilfsstoffe: Calciumsulfat, Maisstärke, Polyvidon, Magnesiumstearat, Hypromellose, Macrogol 400, Eisenoxid (E172), Titandioxid (E171), Pfefferminz Aroma [152 (03/2021)] Hinweis zu ungeeigneten Hilfsstoffen: im Alter <2 J nur bei fehlender Alternative einsetzen (ungeeignet: Pfefferminz Aroma <2 J; Polyvidon und Titandioxid <28 T) [159, 254, 255 (03/2021)]
Zerkleinerbarkeit	Teilbarkeit: ja [159, 225 (10/2023)] Bruchrille: nein [85 (10/2023)] Zermösern: ja [152 (10/2023)] Suspendieren / Auflösen: ja [152 (10/2023)] Bemerkungen: Eine Susp kann durch Zermösern der Tabl und Aufnahme in etwas Glycerin und Verdünnung in einem Sirup hergestellt werden. [152 (10/2023)]
Zulassung bei Kindern	ja, keine klaren Altersangaben [152 (03/2021)]
Lagerbedingungen	bei RT lagern [152 (08/2021)]

Only in the German and French PEDEdose version for users in Switzerland, you can find the «Product specific remarks» regarding the selected product below the indications. In this field, additional information about the selected product is displayed (e.g. «preservatives / excipients», «divisibility », «storage conditions»). There aren't «Product specific remarks» for all products.

7.2.3.3 General doses

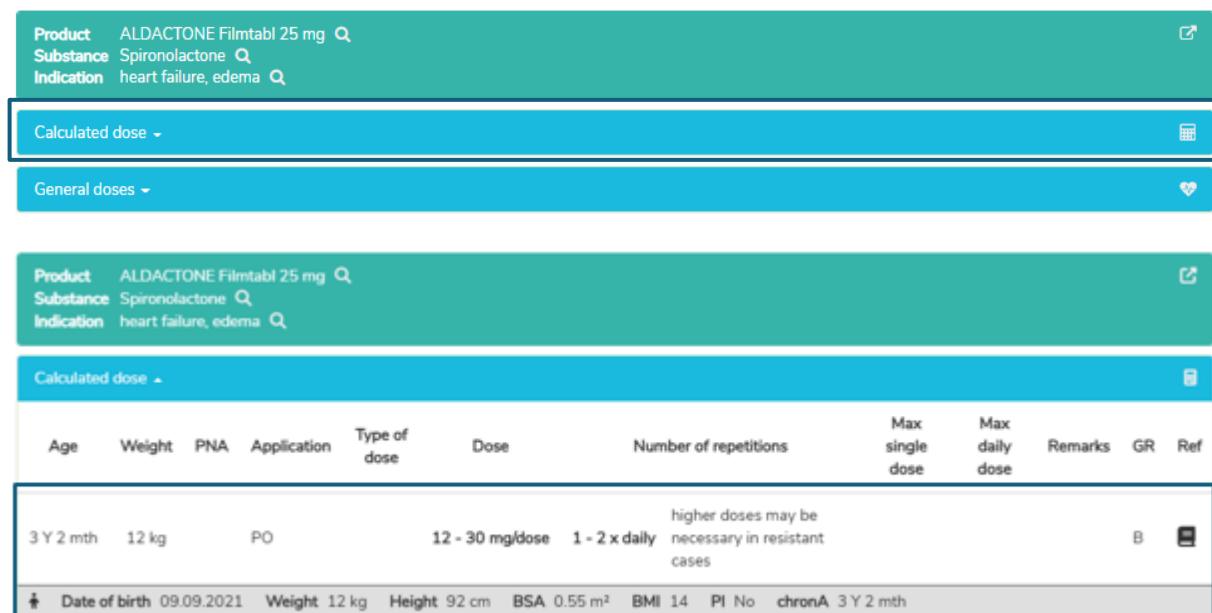
Selecting an indication (in this case «heart failure, edema») opens the window «General doses», where all dosages for the selected product are displayed.

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

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

7.2.3.4 Calculated dose

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



Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref
3 Y 2 mth	12 kg	PO		12 - 30 mg/dose	1 - 2 x daily	higher doses may be necessary in resistant cases			B		
Date of birth 09.09.2021 Weight 12 kg Height 92 cm BSA 0.55 m ² BMI 14 PI No chronA 3 Y 2 mth PMA 40 weeks											

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

Below the section «Calculated dose», the following patient data are displayed in the grey bar: «Date of birth», «Weight», «Height», «BMI», body surface area («BSA»), preterm infant («PI») and chronological age («chronA»). For preterm infants instead of the chronological age the gestational age («GA») at birth and the post-menstrual age («PMA») as well as the post-natal age («PNA») or the corrected age («corrA») are displayed. For former preterm infants with a PMA between 40 and 44 weeks, both the corrected and the postmenstrual age are displayed. (For premature infants, see also chapter 3.3.)

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

7.2.3.5 Dose conversion

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

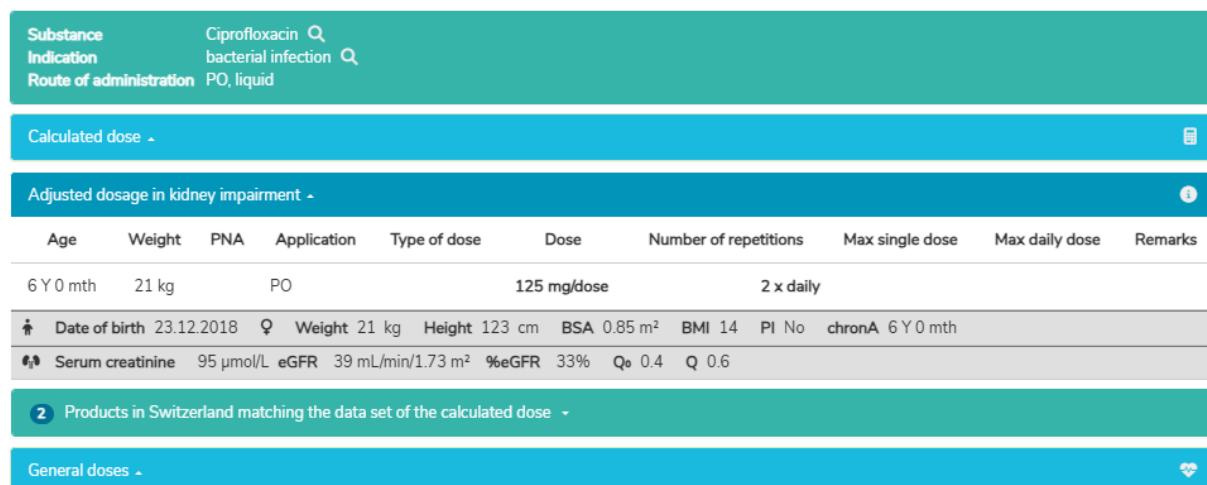
Product BEXIN Tropfen 20.8 mg/ml	Q	☒
Substance Dextromethorphan	Q	☒
Indication dry cough (antitussive)	Q	☒
Calculated dose ▾		
Calculated dose in gtt ▾		
Calculated dose in mL ▾		
General doses ▾		

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

Product BEXIN Tropfen 20.8 mg/ml	Q	☒								
Substance Dextromethorphan	Q	☒								
Indication dry cough (antitussive)	Q	☒								
Calculated dose ▾										
Age 4 Y 1 mth	Weight 17 kg	Application PO	Type of dose	Dose 6.3 mg/dose	Number of repetitions 1 - 4 x daily	Max single dose	Max daily dose	Remarks	GR	Ref (A)
Date of birth 21.10.2020 Weight 17 kg Height 108 cm BSA 0.71 m ² BMI 15 PI No chronA 4 Y 1 mth										
Calculated dose in gtt ▾										
Age 4 Y 1 mth	Weight 17 kg	Application PO	Type of dose	Dose 7.5 gtt/dose	Number of repetitions 1 - 4 x daily	Max single dose	Max daily dose	Remarks	GR	Ref (A)
Date of birth 21.10.2020 Weight 17 kg Height 108 cm BSA 0.71 m ² BMI 15 PI No chronA 4 Y 1 mth										
Calculated dose in mL ▾										
Age 4 Y 1 mth	Weight 17 kg	Application PO	Type of dose	Dose 0.3 mL/dose	Number of repetitions 1 - 4 x daily	Max single dose	Max daily dose	Remarks	GR	Ref (A)
Date of birth 21.10.2020 Weight 17 kg Height 108 cm BSA 0.71 m ² BMI 15 PI No chronA 4 Y 1 mth										

7.3 Calculating the adjusted dosage in patients with kidney impairment

Similar to the calculation without kidney impairment (chapter 7.2), the window with the dosages opens by clicking on «Save» after entering the patient data.



The screenshot shows the PEDEus software interface with the following sections:

- Substance:** Ciprofloxacin Q
- Indication:** bacterial infection Q
- Route of administration:** PO, liquid
- Calculated dose:** 125 mg/dose, 2 x daily
- Adjusted dosage in kidney impairment:**
 - Products in Switzerland matching the data set of the calculated dose:** 2 items
- General doses:** (with a heart icon)

The individually adjusted dosage is displayed under «Adjusted dosage in kidney impairment», provided that an adjusted dosage can be calculated or is necessary.

Clicking on «Calculated dose» opens a window with the calculated dosage for the patient whose data was entered in the «Patient data» field, but for normal kidney function.

Clicking on «General doses» opens a window with the general dosages for patients with normal kidney function for all age groups.

7.3.1 Display of the adjusted dosage

The individually adjusted dosage is displayed under «Adjusted dosage in kidney impairment», provided that an adjusted dosage can be calculated or is necessary. A dosage is adjusted if the glomerular filtration rate as a percentage of the reference value (%eGFR) is between 8 and 75% and the individual elimination capacity Q is less than or equal to 0.8. If the %eGFR is 75% or more or if Q is greater than 0.8, the dosage does not need to be adjusted, i.e. the normal dosage can be administered to the patient. If the %eGFR is below 8%, no adjusted dosage is calculated, but a message appears indicating that a renal replacement therapy should be considered. The suggested adjusted dosages are subject to certain uncertainties (estimated glomerular filtration rate, Q_0 value of the active substance, GFR reference values). This is also indicated by the info button behind the title «Adjusted dosage in kidney impairment».

Just below the adjusted dosage, comments on the adjustment are displayed, e.g. that the active substance is nephrotoxic or contraindicated below a certain GFR threshold or an explanation of why no adjusted dosage is calculated. Also, if the product information for healthcare professionals contains a different recommendation regarding adjustment in patients with kidney impairment, this is mentioned here. If the active substance is contraindicated below a certain GFR threshold value and the individual eGFR is below this threshold value, the contraindication is displayed in red. If the individual

eGFR is just above the threshold value (less than an additional 10 mL/min/1.73 m²), the contraindication is displayed in orange. If the individual eGFR is higher or cannot be calculated, the contraindication is displayed in a neutral colour.

In addition to the other patient data, the following patient data is displayed in the grey bar at the bottom of the section «Adjusted dosage in kidney impairment»: «serum creatinine» or «cystatin C», estimated glomerular filtration rate («eGFR»), eGFR as a percentage of the GFR reference value («%eGFR»), extrarenal elimination fraction («Q₀») and individual elimination capacity («Q»).

For active substances for which the dose is adjusted, the dose, the maximum single dose and the maximum daily dose are reduced accordingly. The frequency of administration remains unchanged.

Substance	Ciprofloxacin 									
Indication	bacterial infection 									
Route of administration	PO, liquid									
Calculated dose 										
Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR Ref
6 Y 0 mth	21 kg		PO		210 mg/dose					B 
⌚ Date of birth	23.12.2018	♀	Weight	21 kg	Height	123 cm	BSA	0.85 m ²	BMI	14 PI No chronA 6 Y 0 mth
② Products in Switzerland matching the data set of the calculated dose 										
Adjusted dosage in kidney impairment 										
Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	
6 Y 0 mth	21 kg		PO		125 mg/dose					
⌚ Date of birth	23.12.2018	♀	Weight	21 kg	Height	123 cm	BSA	0.85 m ²	BMI	14 PI No chronA 6 Y 0 mth
⌚ Serum creatinine	95 µmol/L	eGFR	39 mL/min/1.73 m ²	%eGFR	33%	Q ₀ 0.4	Q 0.6			
② Products in Switzerland matching the data set of the calculated dose 										

For active substances for which the frequency of administration is adjusted, the dosing interval is extended accordingly (rounded to whole hours). The dose and the maximum single dose remain unchanged.

Substance Gentamicin Q, bacterial infection, severe Q
 Indication
 Route of administration IV, parenteral

Calculated dose ▾

Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref
4 Y 8 mth	16 kg		IV		120 mg/dose	1 x daily			by inf	D	

⌚ Date of birth 12.05.2020 ♂ Weight 16 kg PI No chronA 4 Y 8 mth

ⓘ You must enter the height to be able to calculate the BMI.

ⓘ 3 Products in Switzerland matching the data set of the calculated dose ▾

Adjusted dosage in kidney impairment ▾

Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks
4 Y 8 mth	16 kg		IV		120 mg/dose	every 65 h			by inf

Nephrotoxicity This active ingredient is potentially nephrotoxic.

⌚ Date of birth 12.05.2020 ♂ Weight 16 kg PI No chronA 4 Y 8 mth

ⓘ Cystatin C 1.9 mg/L eGFR 41 mL/min/1.73 m² %eGFR 34% Q₀ 0.04 Q 0.37

7.3.2 Display if no adjusted dosage has been calculated

If the dosage cannot be adjusted or an adjustment is not necessary, only the individual calculated dosage for normal kidney function is displayed for the patient whose data was entered. Also, the reasons why no dosage adjustment could be made or why a dosage adjustment is not necessary are given.

Dosage adjustment not possible:

Substance Fluconazole Q, candidiasis (systemic) Q
 Indication
 Route of administration PO, liquid

Calculated dose ▾

Adjusted dosage in kidney impairment ▾

No dosage adjustment using cystatin C can be calculated for children <12 mth.

⌚ Date of birth 07.08.2024 ♀ Weight 7 kg PI No chronA 5 mth

ⓘ Cystatin C 1.9 mg/L Q₀ 0.2

Dosage adjustment not necessary:

Substance Fluconazole Q
 Indication candidiasis (systemic) Q
 Route of administration PO, liquid

Calculated dose ▾

Adjusted dosage in kidney impairment ▾

No dosage adjustment necessary as kidney function is normal.

⌚ Date of birth	23.05.2020	♀	Weight	15 kg	Height	106 cm	BSA	0.66 m ²	BMI	13	PI No	chronA	4 Y 7 mth
⌚ Serum creatinine	31 µmol/L	eGFR	103 mL/min/1.73 m ²	%eGFR	86%	Q ₀	0.2						

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

In this case, the normal calculated dosage applies and the «Calculated dose» accordion must be opened by clicking on it to display the dosage.

Single and loading doses:

The dosage does not need to be adjusted for single and loading doses; the normal dose is therefore listed under the adjusted dosages.

Substance Fluconazole Q
 Indication candidiasis (systemic) Q
 Route of administration IV, parenteral

Calculated dose ▾

Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref
4 Y 7 mth	15 kg	IV		loading dose	180 mg/dose				as a single dose, start the maintenance dosage 24 h after the loading dose; by inf	D	█
4 Y 7 mth	15 kg	IV		maintenance	90 mg/dose	1 x daily			first maintenance dose 24 h after the loading dose; by inf	D	█

⌚ Date of birth 23.06.2020 ♀ Weight 15 kg Height 106 cm BSA 0.66 m² BMI 13 PI No chronA 4 Y 7 mth

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

Adjusted dosage in kidney impairment ▾

Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks
4 Y 7 mth	15 kg	IV		loading dose	180 mg/dose				as a single dose, start the maintenance dosage 24 h after the loading dose; by inf
4 Y 7 mth	15 kg	IV		maintenance	49 mg/dose	1 x daily			first maintenance dose 24 h after the loading dose; by inf

Single or loading doses do not need to be adjusted.

⌚ Date of birth	23.06.2020	♀	Weight	15 kg	Height	106 cm	BSA	0.66 m ²	BMI	13	PI No	chronA	4 Y 7 mth
⌚ Serum creatinine	61 µmol/L	eGFR	52 mL/min/1.73 m ²	%eGFR	44%	Q ₀	0.2	Q	0.55				

7.3.3 Display when searching by active substance or indication

When searching by substance or indication, a list of linked products in Switzerland that match all or individual dosage datasets is displayed below the «General doses» window for users in Switzerland. Below the «Adjusted dosage in kidney impairment» window, however, only the products that match the dataset used for the calculation appear (see also chapter 7.2).

Substance Ciprofloxacin

 Indication bacterial infection

 Route of administration PO, liquid

Calculated dose

Adjusted dosage in kidney impairment

Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks
6 Y 0 mth	21 kg		PO		125 mg/dose	2 x daily			
Date of birth 23.01.2019 ♀ Weight 21 kg Height 123 cm BSA 0.85 m ² BMI 14 PI No chronA 6 Y 0 mth									
Serum creatinine 95 µmol/L eGFR 39 mL/min/1.73 m ² %eGFR 33% Qe 0.4 Q 0.6									

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

CIPROXIN Gran 10 g/100ml c Solv f Susp	Ciprofloxacin	
CIPROXIN Gran 5 g/100ml c Solv f Susp	Ciprofloxacin	

If no adjusted dosage can be calculated or is necessary, products that match the dataset are only displayed below the «Calculated dose».

7.3.4 Display when searching by product

If the product is searched for and alternative units are available for the corresponding product, the adjusted dosage is also converted by the calculator from the initial unit to an alternative unit (dispensing unit) (e.g. from mg to drops or mL), if kidney function is impaired (see also chapter 7.2.3.5). This «Adjusted dosage in alternative units» is displayed below the «Adjusted dosage in kidney impairment».

Product	CIPROXIN Gran 5 g/100ml c Solv f Susp	Q	
Substance	Ciprofloxacin	Q	
Indication	bacterial infection	Q	

Calculated dose	
-----------------	--

Calculated dose in mL	
-----------------------	--

Adjusted dosage in kidney impairment	
--------------------------------------	--

Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks
3 Y 3 mth	14.5 kg		PO		85 mg/dose		2 x daily		

Adjusted dosage in kidney impairment in mL									

If no adjusted dosage can be calculated or is necessary, only the "Calculated dose in alternative units" is displayed below the "Calculated dose".

Product	CIPROXIN Gran 5 g/100ml c Solv f Susp	Q	
Substance	Ciprofloxacin	Q	
Indication	bacterial infection	Q	

Calculated dose	
-----------------	--

Calculated dose in mL	
-----------------------	--

Age	Weight	PNA	Application	Type of dose	Dose	Number of repetitions	Max single dose	Max daily dose	Remarks	GR	Ref			
3 Y 3 mth	14.5 kg		PO		2.9 mL/dose		2 x daily			B				
	Date of birth	22.10.2021	♀	Weight	14.5 kg	Height	99 cm	BSA	0.63 m ²	BMI	15	PI No	chronA	3 Y 3 mth

Adjusted dosage in kidney impairment	
--------------------------------------	--

No dosage adjustment necessary, as kidney function is sufficient for the elimination of this active ingredient.

	Date of birth	22.10.2021	♀	Weight	14.5 kg	Height	99 cm	BSA	0.63 m ²	BMI	15	PI No	chronA	3 Y 3 mth
	eGFR	85 mL/min/1.73 m ²	%eGFR	71%	Q _d	0.4	Q	0.83						

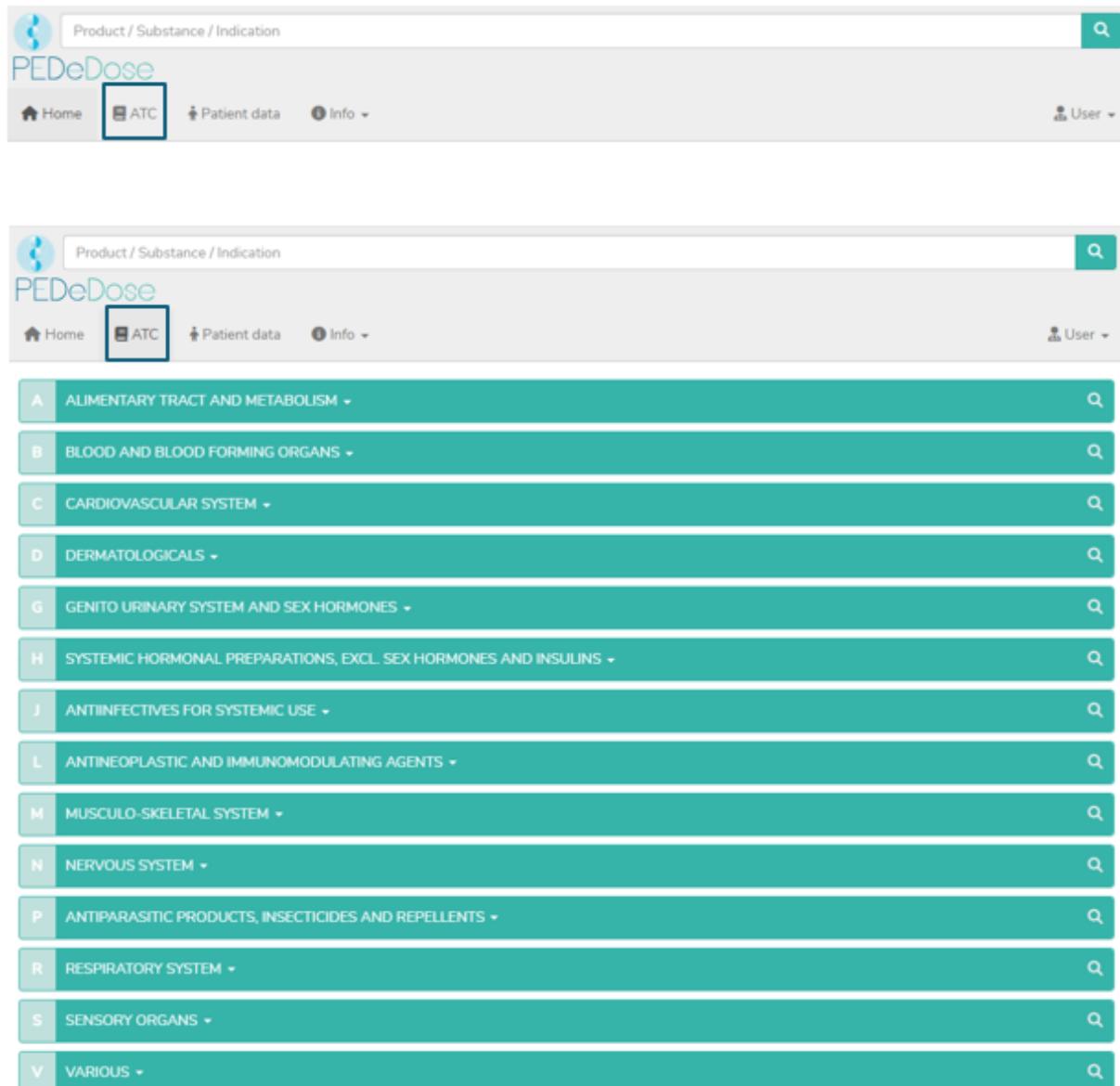
Adjusted dosage in kidney impairment in mL	
--	--

No dosage adjustment necessary, as kidney function is sufficient for the elimination of this active ingredient.

	Date of birth	22.10.2021	♀	Weight	14.5 kg	Height	99 cm	BSA	0.63 m ²	BMI	15	PI No	chronA	3 Y 3 mth
	eGFR	85 mL/min/1.73 m ²	%eGFR	71%	Q _d	0.4	Q	0.83						

7.4 ATC code

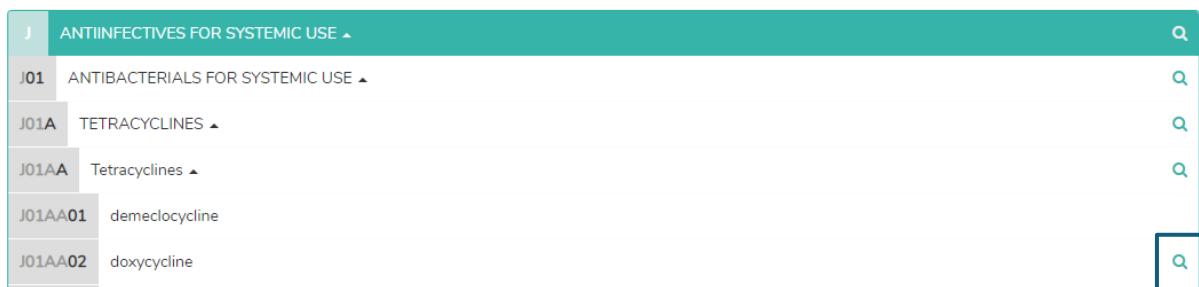
By clicking the «ATC» button at the top of the page, the ATC code selection drops down, see below.



The screenshot shows the PEDEus software interface with the 'ATC' button highlighted. A dropdown menu lists 14 categories of ATC codes, each with a magnifying glass icon for search:

- A ALIMENTARY TRACT AND METABOLISM
- B BLOOD AND BLOOD FORMING ORGANS
- C CARDIOVASCULAR SYSTEM
- D DERMATOLOGICALS
- G GENITO URINARY SYSTEM AND SEX HORMONES
- H SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS
- J ANTIINFECTIVES FOR SYSTEMIC USE
- L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
- M MUSCULO-SKELETAL SYSTEM
- N NERVOUS SYSTEM
- P ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS
- R RESPIRATORY SYSTEM
- S SENSORY ORGANS
- V VARIOUS

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

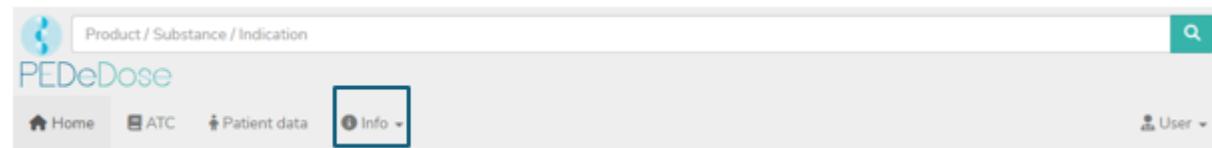


The screenshot shows a search results list for 'Tetracyclines'. The results are organized into levels: J01 (Antibacterials for systemic use), J01A (Tetracyclines), J01AA (Tetracyclines), J01AA01 (demeclocycline), and J01AA02 (doxycycline). Each result has a magnifying glass icon to its right, indicating it is a selectable item.

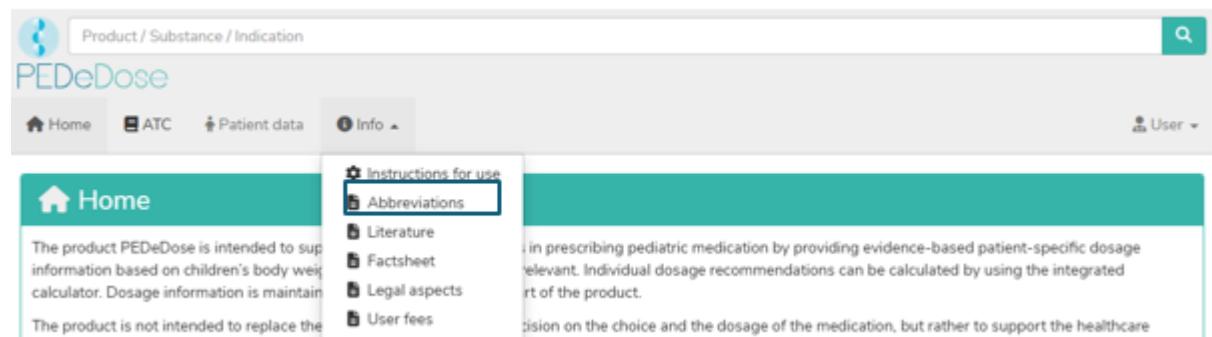
The active substances not marked with a magnifying glass are not included in PEDeDose.

7.5 Abbreviations

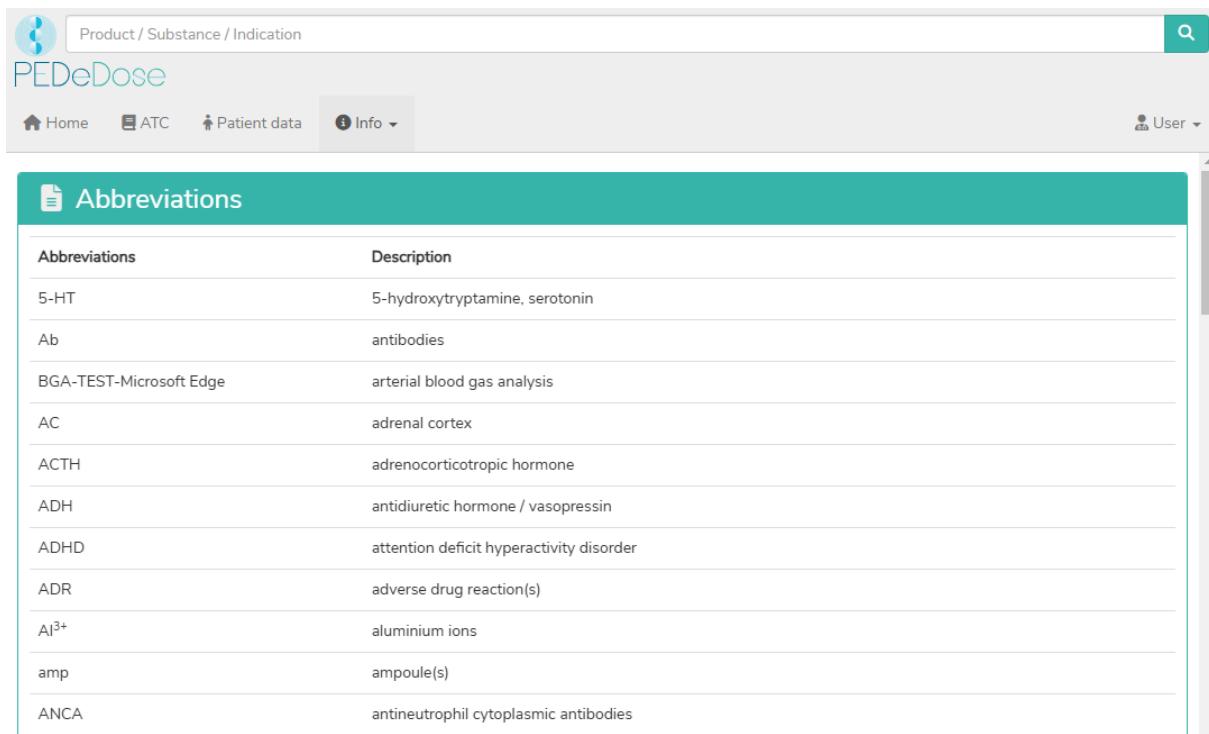
Click on the «Info» button at the top of the page to open a drop-down menu. Selecting «Abbreviations» opens the «Abbreviations» page, which lists all the abbreviations used in PEDeDose, see below.



The screenshot shows the PEDeDose interface with the 'Info' button highlighted with a blue box. The dropdown menu is open, showing options: 'Instructions for use', 'Abbreviations' (which is selected and highlighted with a blue box), 'Literature', 'Factsheet', 'Legal aspects', and 'User fees'.



The screenshot shows the 'Abbreviations' page. The left sidebar has a 'Home' button and a message: 'The product PEDeDose is intended to support healthcare professionals in prescribing pediatric medication by providing evidence-based patient-specific dosage recommendations. Individual dosage recommendations can be calculated by using the integrated calculator of the product. The product is not intended to replace the healthcare professional's judgment on the choice and the dosage of the medication, but rather to support the healthcare professional in making informed decisions.' The main content area shows a list of abbreviations: 'Instructions for use', 'Abbreviations' (selected and highlighted with a blue box), 'Literature', 'Factsheet', 'Legal aspects', and 'User fees'. The text in the main content area is: 'in prescribing pediatric medication by providing evidence-based patient-specific dosage relevant. Individual dosage recommendations can be calculated by using the integrated of the product. on the choice and the dosage of the medication, but rather to support the healthcare'.



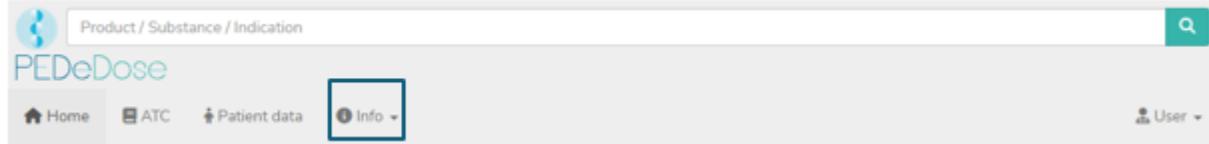
Abbreviations

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

7.6 Literature

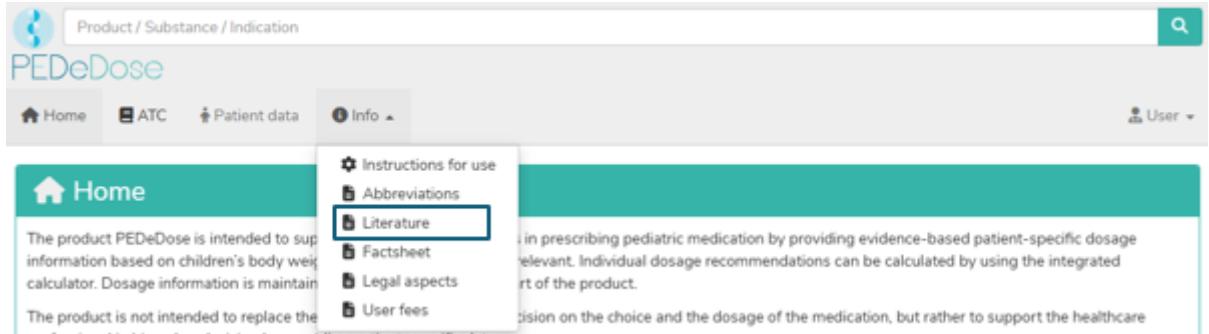
Click on the «Info» button at the top of the page to open a drop-down menu. Selecting «Literature» opens the «Literature» page, which lists all references used in PEDeDose.

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



Info

- Instructions for use
- Abbreviations
- Literature**
- Factsheet
- Legal aspects
- User fees



Home

The product PEDeDose is intended to support healthcare professionals in their decision-making process. It provides evidence-based patient-specific dosage information based on children's body weight calculator. Dosage information is maintained in a central database and updated regularly. The product is not intended to replace the professional judgment of healthcare providers.

Instructions for use

in prescribing pediatric medication by providing evidence-based patient-specific dosage information. Individual dosage recommendations can be calculated by using the integrated calculator of the product.

Abbreviations

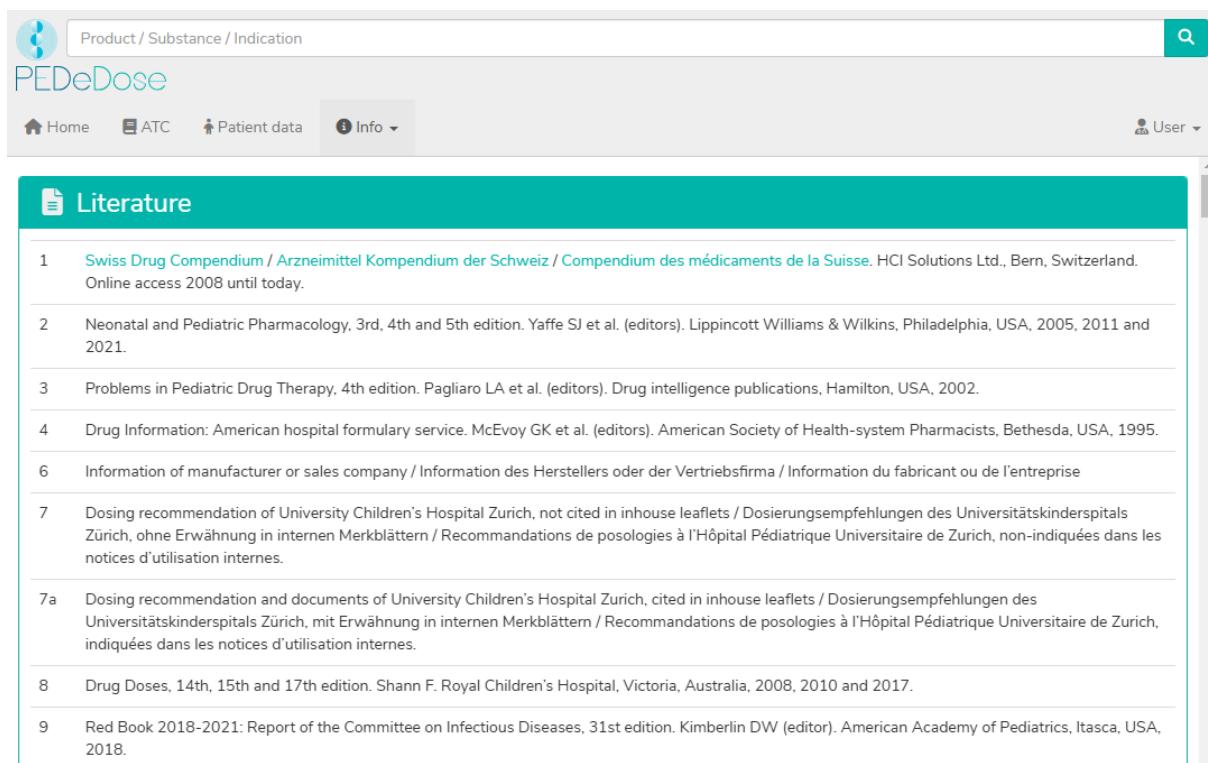
Literature

Factsheet

Legal aspects

User fees

dition on the choice and the dosage of the medication, but rather to support the healthcare



The screenshot shows the PEDEose software interface. At the top, there is a search bar with the placeholder "Product / Substance / Indication" and a magnifying glass icon. Below the search bar, the text "PEDEose" is displayed. A navigation bar contains links for "Home", "ATC", "Patient data", "Info", and "User". The main content area is titled "Literature" and lists the following references:

- 1 Swiss Drug Compendium / Arzneimittel Kompendium der Schweiz / Compendium des médicaments de la Suisse. HCI Solutions Ltd., Bern, Switzerland. Online access 2008 until today.
- 2 Neonatal and Pediatric Pharmacology, 3rd, 4th and 5th edition. Yaffe SJ et al. (editors). Lippincott Williams & Wilkins, Philadelphia, USA, 2005, 2011 and 2021.
- 3 Problems in Pediatric Drug Therapy, 4th edition. Paglialo LA et al. (editors). Drug intelligence publications, Hamilton, USA, 2002.
- 4 Drug Information: American hospital formulary service. McEvoy GK et al. (editors). American Society of Health-system Pharmacists, Bethesda, USA, 1995.
- 6 Information of manufacturer or sales company / Information des Herstellers oder der Vertriebsfirma / Information du fabricant ou de l'entreprise
- 7 Dosing recommendation of University Children's Hospital Zurich, not cited in inhouse leaflets / Dosierungsempfehlungen des Universitätskinderspitals Zürich, ohne Erwähnung in internen Merkblättern / Recommandations de posologies à l'Hôpital Pédiatrique Universitaire de Zurich, non-indiquées dans les notices d'utilisation internes.
- 7a Dosing recommendation and documents of University Children's Hospital Zurich, cited in inhouse leaflets / Dosierungsempfehlungen des Universitätskinderspitals Zürich, mit Erwähnung in internen Merkblättern / Recommandations de posologies à l'Hôpital Pédiatrique Universitaire de Zurich, indiquées dans les notices d'utilisation internes.
- 8 Drug Doses, 14th, 15th and 17th edition. Shann F. Royal Children's Hospital, Victoria, Australia, 2008, 2010 and 2017.
- 9 Red Book 2018-2021: Report of the Committee on Infectious Diseases, 31st edition. Kimberlin DW (editor). American Academy of Pediatrics, Itasca, USA, 2018.

8 Complaints and feedback

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

9 Contact information

9.1 General data

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 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 V3.0 2025-02 2030-02	
	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: CHRN-MF-20000718 SRN: CH-MF-000017885
	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.

12 Annexes

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