Instructions for use

PEDeMed

Clinical Decision Support for the Preparation and Administration of Parenteral Drugs

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1 General

The instruction for use contains detailed instructions on how to use the PEDeMed application. PEDeMed is a clinical decision support tool, which provides step-by-step instructions for the safe preparation and administration of parenteral drugs.

All data displayed in PEDeMed are retrieved from the PEDeDose web service. PEDeDose is a CE-certified Class IIa medical device under Medical Devices Regulation (MDR) and performs all calculations.

The latest version of this document can be found by clicking on Instruction for use at the bottom right corner of the application.

2 Manufacturer

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3 Copyright

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

4 Use specification

4.1 Intended use

The application PEDeMed is intended to support healthcare professionals in the preparation and administration of parenteral drugs. It displays calculated volumes and specifies appropriate solvents and diluents based on the selected route of administration, the mode of administration and the patient-specific dosages. PEDeMed is intended to be used for pediatric patients, including neonates (term and preterm infants), infants, toddlers, children, adolescents as well as for adults.

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

4.2 Intended users and prerequisites

PEDeMed is intended exclusively for use by healthcare professionals (e.g. nurses, pharmacists). Basic training on the preparation of parenteral medication is a prerequisite for using PEDeMed.

4.3 Use environment

PEDeMed is intended to be used as standalone application via website. Intended users will have access to PEDeMed in different environments, including access from hospitals, pharmacies or at home.

5 Language

PEDeMed is available in German, French and English. The language is selected automatically based on the predefined language of the used browser. If the predefined language of the browser is none of the mentioned languages, PEDeMed will be displayed in French.

6 System requirements

PEDeMed is designed for use on devices with a minimal screen area of 1800 pixels. The PEDeMed application runs on the most common internet browsers (e.g. Chrome, Edge, Safari) in the respective most current versions. It is advisable for users to install an anti-virus software on their system.

7 Registration and login

The access to the application is restricted by state-of-the-art login solutions.

Individual users must register to access the application. There are two alternative login processes: PEDeus login or single sign-on (SSO) via Swiss RX Login or Microsoft 365. The login via Swiss RX 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).

The application can be accessed at the following web address: https://www.pedemed.ch. PEDeMed is available 24 hours a day / 365 days a year, unforeseen circumstances reserved.

8 Using PEDeMed

The PEDeMed application consists of two pages:

- data entry page
- preparation instruction page

In the data entry page, the user selects the product and provides prescription information. In the preparation instruction page, the user can see the step-by-step instruction for the preparation and administration of the prescribed product.

8.1 Symbols

The following symbols are used in the system:

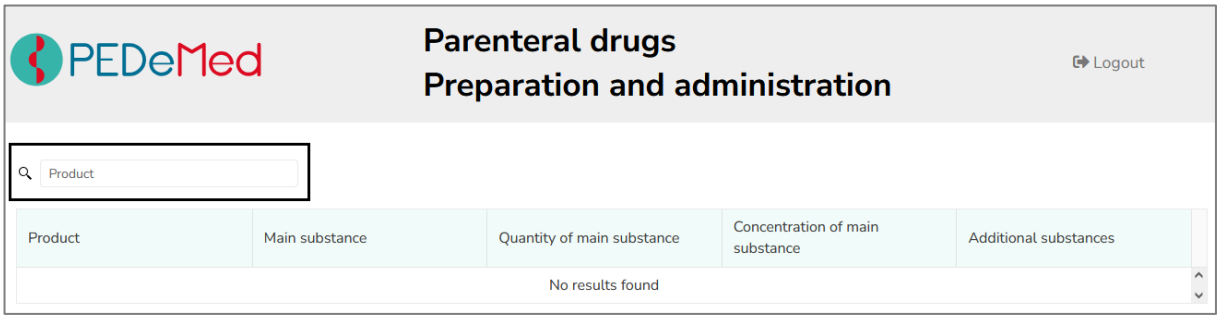
	Magnifying glass: visible next to the search field used to search and select a product.
	Pencil: operating function that can be found besides the selected product or dosage and allows the modification of the entered information.
	Info button: clicking on it opens a window which displays information related to the specific preparation step. The information window can be closed again by clicking on the cross (X) at the upper right corner.
	Warning symbol: warning text is displayed beside it.

8.2 Data entry

The initial view of the PEDeMed application allows the selection of the product. As soon as the product is selected, the user can enter prescription related information.

8.2.1 Product search

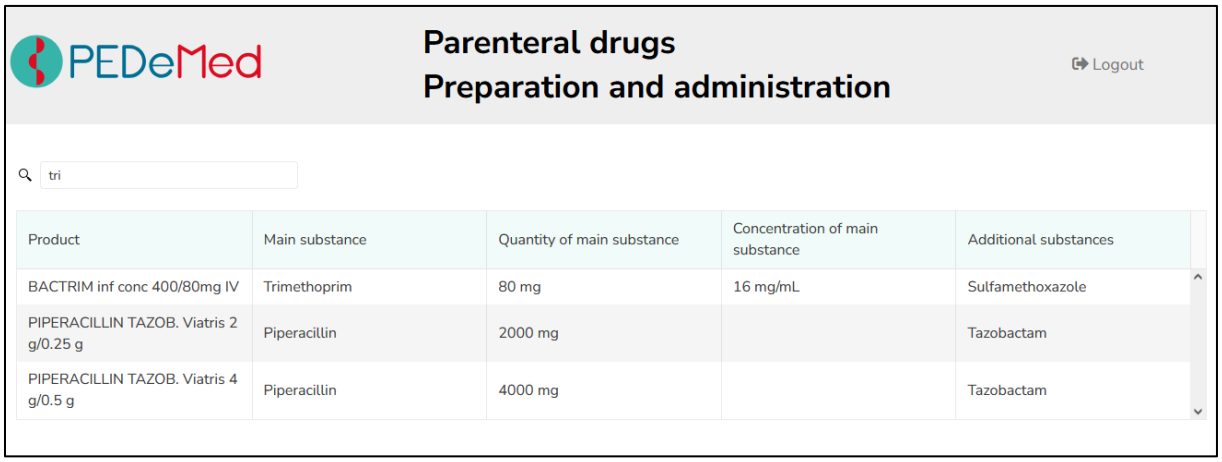
The search field is located next to the magnifying glass and is used to initiate the product selection.



Either a substance name or a product name can be entered in the field. A search result is displayed automatically after three characters are entered and is continuously updated when further text is added. The search function is not case sensitive.

The search result will list all products containing the search text in the main substance or product name. For example, if “Amoxicillin” is entered, the search will return all products containing the main substance Amoxicillin, including combinations with Clavulanic acid, as well as all products containing Amoxicillin in their name.

The list of products resulting from the search are displayed in a table just below the search field. The table displays the following information: product name, name of main substance, quantity of main substance (in case of dry substances), concentration of main substance (in case of liquid products) and additional substances if applicable. The user selects a product by clicking on it.

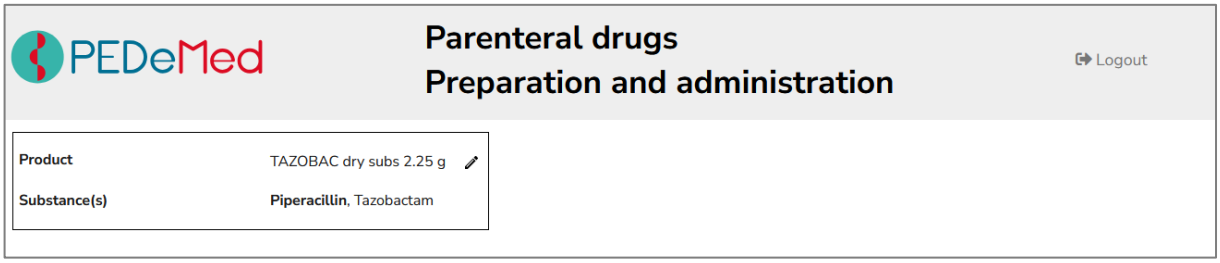


8.2.2 Prescription data

In this page the user provides the prescription information relevant for the parenteral preparation and administration.

The selected product is displayed on top of the page. By clicking on the pencil besides the product, the user can go back to the product search and initiate a new product selection.

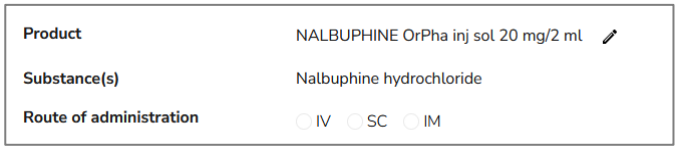
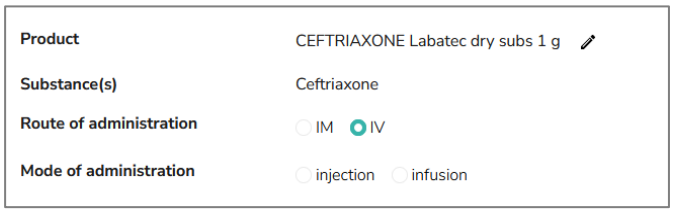
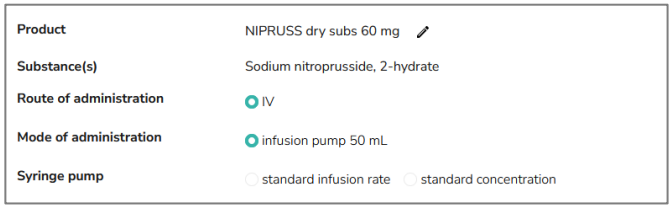
The name of the substance contained in the selected product is displayed just under the product name. If the selected product contains more than one substance, all substances are listed, but only the main substance will be bold.

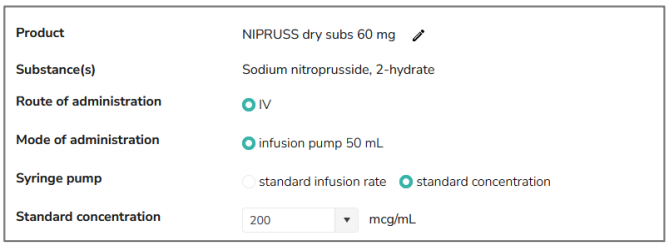
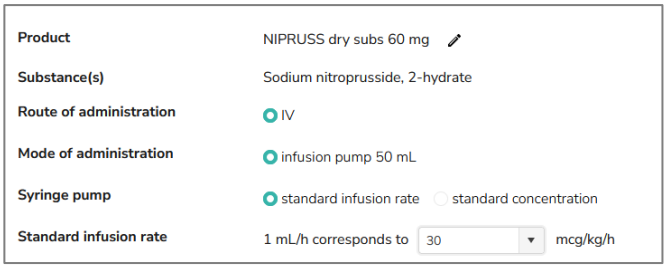


Thereafter, the user enters prescription data, in a stepwise manner. The following applies for the data entry:

- If more than one possible option exists for a certain parameter, the user needs to select one to continue to the next step.
- In case only one option exists, it will be preselected, and the next parameter will be presented automatically.
- Changes can be introduced for all levels; if a parameter is modified, all subsequent entries are reset.

The required parameters vary depending on the product selected and input provided. All possible required parameters are included in the table below.

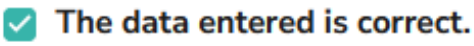
Parameters	Description	Comment
Route of administration	In the subsequent also called ROA Examples: IV, SC, IM 	All possible ROA for the selected product are displayed.
Mode of administration	In the subsequent also called MOA Possible MOA are: - Injection - Infusion - Long time infusion - Infusion pump → the administration of long time infusions using an infusion pump considers the final volume of the preparation.  Example: Ceftriaxone can be administered as IV injection or infusion.	MOA Injection and Infusion are prescribed as quantity per dose MOA Long time infusion and Infusion pump are prescribed as quantity per time unit
Syringe pump standard	In case of MOA Infusion pump the user must select among the following two alternatives: - standard concentration - standard infusion rate Example: Nipruss is often administered using an infusion pump. The user selects the MOA infusion pump, considering the final volume of the preparation and the standard.  In case of standard concentration, the patient-specific dosage is administered by adjusting the infusion rate. In case of standard infusion rate, if the patient-specific dosage is different to the standard dosage or the	Standard concentration: the concentration of the infusion is predefined (standard). Standard infusion rate: the concentration of the infusion is defined by the body weight of the patient; a standard rate (usually 1 mL/hour) is required to administer a standard dosage.

Parameters	Description	Comment
	maximal possible concentration of the infusion is reached, the infusion rate must be adjusted.	
Standard infusion concentration	Concentration of the infusion administered using the infusion pump 	Only required for MOA infusion pump AND standard concentration
Standard infusion rate	Dosage per body weight that corresponds to an infusion rate of 1 mL/hour 	Only required for MOA infusion pump AND standard infusion rate
Dosage	Prescribed dosage in the predefined unit; decimal numbers with a maximum of 3 digits after the comma are allowed	For long time infusion and infusion pump, the time unit for the defined dosage, i.e. min or hours, must be selected.
Patient weight	Patient weight in kg Values allowed: 0.250 – 200 kg	Only required for MOA long time infusion or infusion pump
Transfer set	If the product is a dry substance and the prescribed dose correlates to the content of one or more product units, the user can request the preparation instruction using a transfer set.	Only applicable for MOA infusion
If all requested data has been completed, the button “Continue” is displayed.		

Parameters	Description	Comment
Venous access	If the product can only be administered via central venous access the information is displayed**.** If different possibilities exist for central or peripheral administration, the user will be presented with the choice. If no information is displayed, the product can be administered via central or peripheral venous access.	Only in case of ROA IV
Infusion duration	Allows the selection of the infusion duration. If only one infusion duration is possible, this will be displayed.	Only if MOA is infusion

8.2.3 Data confirmation

Before moving to the preparation instruction page, the user must confirm the correctness of the data entered, by clicking the corresponding checkbox as shown below.



If entries need to be modified, the user must uncheck the confirmation box. After the modification is done, a new confirmation is required to continue.

8.2.4 Move to the preparation instructions

To see the preparation instructions, the user must click on the button “Display preparation”. If no preparation for the data entered is available, the following message is displayed in red:

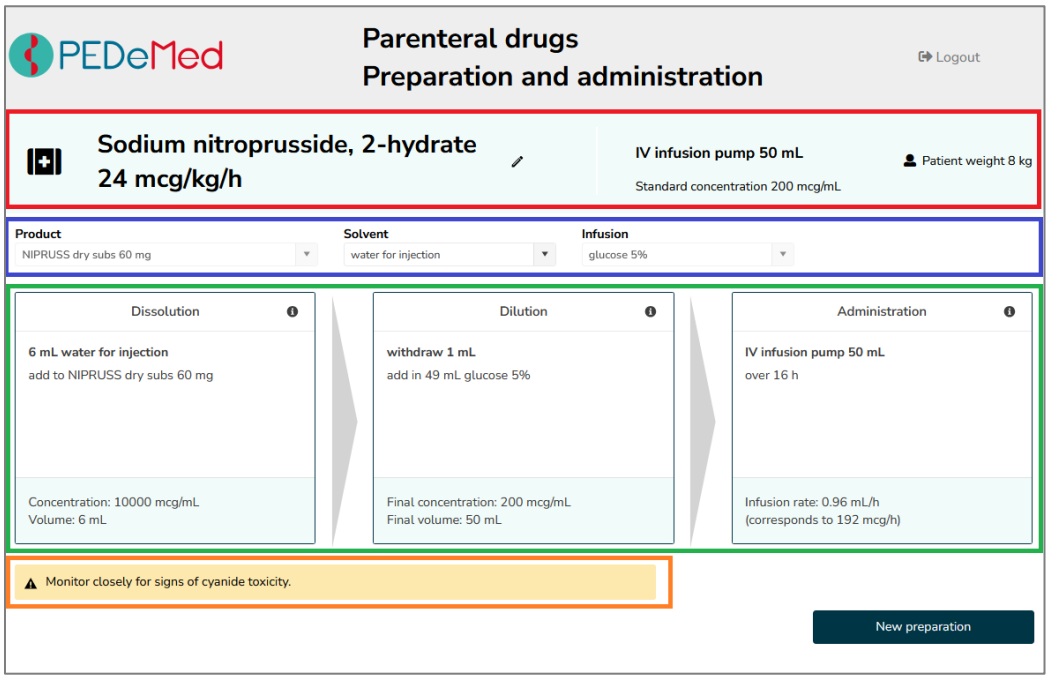
“No matching preparation could be found”.

8.3 Preparation instructions page

The purpose of this page is to display a step-by-step instruction for the preparation and administration of the product.

The preparation page contains the following information:

- prescription information (entry data, in the figure below framed red)
- products needed for the preparation (in the figure framed blue)
- preparation instruction (in the figure framed green)
- warnings (in the figure framed orange)



8.3.1 Prescription information

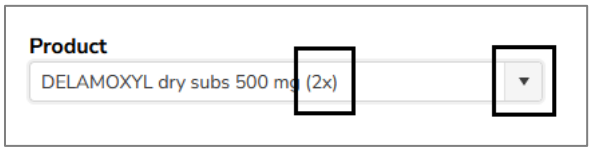
On the left, the name of the main substance and the substance dosage appear. If applicable, secondary substances are also listed. The pencil located beside the dosage allows the user to go back to the data entry page. In the center of the box, the ROA and MOA are displayed. In the case of MOA infusion pump, the selected standard is displayed with either the standard concentration or the standard infusion rate and corresponding dosage per body weight. In case of MOA infusion, the administration duration is displayed. On the right side of the red box, the patient weight is displayed if applicable.

8.3.2 Initial products

Up to four dropdown boxes corresponding to the products needed for the preparations can be displayed in this row, i.e. pharmaceutical product, solvent, intermediate dilution and infusion. The preparation page allows for the selection of alternatives if applicable in any of the four dropdown boxes. If any product is changed, the preparation displayed will change accordingly.

8.3.2.1 Pharmaceutical product

The product box contains the selected pharmaceutical product. Alternative pharmaceutical products (products with the same Swissmedic number: containing the same substance(s) and registered under the same license), can be found in the dropdown. The number of product units needed for the preparation is shown in round brackets, if it differs from 1.



If an alternative product is selected and no preparation is available for the prescription data entered, the following message will be displayed in red:

“No matching preparation could be found, please select another product”.

8.3.2.2 Solvent, dilution and infusion

The solvent dropdown appears only in case of dry products.

The dilution dropdown appears only in case an intermediate dilution is needed for the preparation.

The infusion dropdown includes the infusion volume.

8.3.3 Preparation and administration instructions

Up to four boxes can be displayed under the preparation and administration instructions, i.e. dissolution, intermediate dilution, dilution and administration. In case of MOA injection, a volume box will be displayed. The instructions for the various steps, as well as the resulting concentrations, are shown in the boxes.

The following principles must be followed:

– Only clear and particle-free solutions may be administered. Normal changes in coloration are indicated in PEDeMed under “Information about dissolution/dilution”.

– From a microbiological point of view, diluted solutions should be administered immediately after preparation, also if the conservation information provided in PEDeMed allows otherwise.

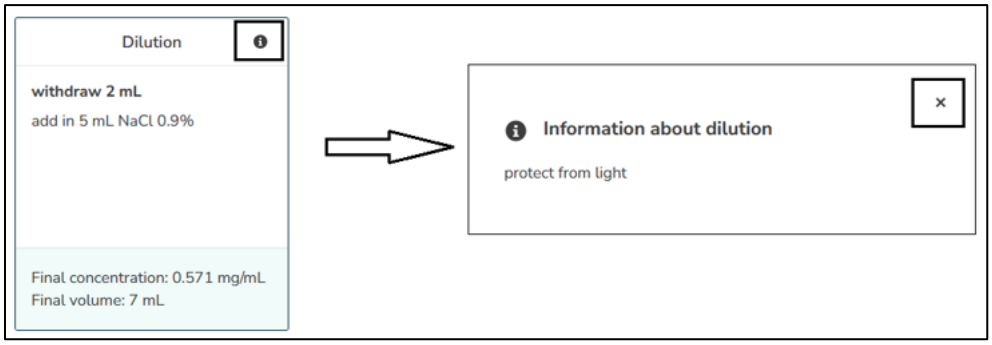
– In PEDeMed, the stability for solutions after each step of the preparation process, is limited to 24 hours, unless a shorter conservation time is allowed because of physical or chemical reasons. However, this conservation time should be considered as maximal total conservation, i.e.: conservation after dissolution + conservation after intermediate/dilution + administration time = max. 24 hours.

– In PEDeMed conservation time is displayed for room temperature and in the refrigerator; however, storage of solutions in the refrigerator should be favored due to hygienic reasons.

– The conservation after dilution displayed in PEDeMed also includes the duration of administration.

8.3.3.1 Info button

Clicking on the info button in any of the instruction boxes opens a window which displays information related to the specific preparation stage or administration.



8.3.4 Warning

If applicable, a warning text is displayed under the preparation and administration instructions, besides the warning symbol.

8.3.5 Start a new preparation

A new preparation can be started by clicking on the button “New preparation”, located at the bottom right of the preparation instruction page.

9 Support and resources

In addition to the instructions for use, a tutorial on PEDeMed is available on the company website https://www.pedeus.ch/.

10 Abbreviations

The list of abbreviations used in PEDeMed can be found in the Abbreviations list (https://www.pedeus.ch/de/pedemed-abkuerzungen-abbreviations-abreviations).

11 Literature

All references used in PEDeMed can be found in the Literature lists (https://www.pedeus.ch/de/pedemed-literatur-literature-reference).

12 News

Important changes in content can be found under PEDeMed News in the following link: News (https://www.pedeus.ch/de/ueber-uns/news/pedemed-news/).

13 Safety and Security

13.1 Warning and remaining risks

The following warnings and precautions must be considered by the PEDeMed user:

- If a user enters incorrect data, the received output may be incorrect.
- The user may miss warnings or relevant information for various reasons (e.g. interruption, distraction).
- It may happen that PEDeMed is temporarily or partially unavailable; for this reason, the PEDeMed user should have at hand alternative information sources to support parenteral drugs preparation, e.g. summary of product characteristics (SmPC) or the so-called parenteral preparation lists, compiled by the pharmacy of the institution.
- As the system is IT-based, performance may be affected by cybercrime.
- Although the preparation is pharmaceutically correct, it may not be suitable for a patient under certain circumstances (e.g., infusion volume in cases of fluid restriction needs). It is the responsibility of the attending physician to prescribe the correct preparation.

All risks associated with PEDeMed have been reduced as far as possible to an acceptable level by appropriate measures. The benefits of PEDeMed clearly outweigh these residual risks.

13.2 Complaints and feedback

We kindly inform you that technical and content-related errors detected in the PEDeMed application must be reported immediately, but no later than 48 hours after detection to PEDeus via email (info@pedeus.ch). Additional feedback on the functionality or content of the application is welcome and can be sent to info@pedeus.ch.

