

29.05.2024

Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue reported to the national competent authority:

Title: When an unknown dosage is prescribed in the administration dialogue, using fractions is not possible.

Internal Reference: MST0021040

Product name and version(s) and UDI-DI:





- ORBIS Medication 03.15.00.00 in ORBIS 84.37.00.00 and higher in Germany, Austria, Switzerland, Luxembourg - Manufacturer: DH Healthcare GmbH.
- ORBIS Medication 03.16.01.00 in ORBIS 84.38.00.00 and higher and ORBIS 85.21.00.00 and higher in France - Manufacturer: DH Healthcare GmbH.
UDI-DI: 4260693990026.


Information:

In ORBIS Medication, following behavior has been observed, that could lead to wrong dosages:



When a drug is prescribed with an unknown dosage and it is defined that each administration needs to be signed separately by the physician, the dosage to be administered has to be entered via the administration panel in the patient chart (see screenshots below). When the user enters fractions (e.g. 1/2 piece), the "fraction-slash" is ignored by the system. If this is overseen by the user and the administration is signed like that, this could lead to wrong dosages for the selected administration (e.g., 12 pieces instead of 1/2 piece):

██████████ 3 mg Tabl. ← → ×


Signed    

 Reschedule

◆ Phenprocoumon


ORAL  




0 - 0 - ? Piece


▼ 

Condition: based on INR
Physician's signature required prior to each administration

Quantity to be administered
21/05/2024 18:00 ? Piece

12 Piece 

Add your comment here   

Cancel  Sign

It is still possible to enter values in decimal digits instead of fractions (e.g., 0,5 piece instead of 1/2) and then sign the administration:

URGENT FIELD SAFETY NOTICE - MST0021040

DH Healthcare GmbH
Konrad-Zuse-Platz 1-3, 53227 Bonn

3 mg Tabl. ← → ×

Signed 📄 ✓ ✗ ○ 🕒

🔄 Reschedule

◆ Phenprocoumon

ORAL 🟢🔴?

0 - 0 - ? Piece

▼ ?

Condition: based on INR
Physician's signature required prior to each administration

Quantity to be administered
21/05/2024 18:00 ? Piece

0,5 Piece ✗

Add your comment here

📄
💾
🗑️

Cancel 🖋️ Sign

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter;
- Release of correction with ORBIS Medication 03.20.00.00 in ORBIS 84.42.00.00.DACHL (release planning: beginning of June 2024), and with ORBIS Medication 03.19.05.xx in 84.41.00.xx.FR (release planning: second half of 2024) and in 85.24.00.xx.FR (release planning: second half of 2024).

Recommended actions to be taken by the customer:

In order to avoid the abovementioned behavior, following actions are recommended:

- Install correction when available.
- As physician in charge to sign administrations, always prescribe in decimal digits instead of fractions if the value of the dose is not a whole number.
- As physician in charge to sign administrations, always check the entered value before signing the administration.
- As a nurse in charge of administering drugs, always check if the prescribed amount is a realistic value.

Please distribute this information to all those who need to be aware of it and confirm the acknowledgement by sending the signed response form.

Regardless of the situation described here, we would like to point out that care providers must always ensure that clinically relevant information, including prescription information, is clearly communicated and that they must use verified information (e.g., from medical devices such as monitoring systems), independent from the software being used.

It is important that you take the actions described in this safety information and acknowledge receipt of this letter.

If the above information does not apply to your hospital or if the device has been transferred to another organization, please indicate this on the attached feedback form and forward this Field Safety Notice to the respective organization.

Thank you for your careful attention to this matter and for your support.

If you have any questions on this matter, please consult our contact person:

Sincerely,

Urgent Field Safety Notice

Feedback Form

We kindly ask you to return this feedback form as soon as possible, but at the latest **within 30 days** after receipt of this letter, to the following e-mail address:

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):

Address:

Reference

MST0021040: When an unknown dosage is prescribed in the administration dialogue, using fractions is not possible

Product reference:

ORBIS Medication

Name (contact person)

Position

Phone number

Date

Signature

- I confirm that I have received and understood the safety information.
- The safety information does not apply to my facility.
- The device was transferred to another organization.

Name and address of the other organization: _____

- Please update our contact information as follows:

Customer / Facility:

Address: