

06.11.2024

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: The date of the first administration is shifted to a date in the future, instead of being scheduled for the next possible date, if repetition is adjusted

Internal Reference: MST0087678

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

- ORBIS Medication 03.17.01.00 in ORBIS 84.39.01.00 and higher in Germany, Austria, Switzerland, and Luxembourg
- ORBIS Medication 03.13.07.00 in ORBIS 84.35.03.05 and ORBIS Medication 03.16.03.00 in ORBIS 85.21.00.01 and higher in France
Manufacturer: DH Healthcare GmbH
UDI-DI: 4260693990026

Information:

A physician prescribes a drug with the first administration scheduled by default for the following day, when the default schedule for this administration having passed.

Example: the daily administration is scheduled at 8 a.m, and the prescription line is created at 2 p.m.

Drug prescription*

HOSPITAL Alerts Measured weight 3.375 kg so 0.2195 m² ?

[Prescription](#) [Indications](#) [Summary](#)

Product(s) & Dose Add a carrier Add a product Add a condition

Drug information - Advice to the physician: Comment AVANT - NEW

Paracetamol 500 mg Tabletten **1 Tbl/take**

Daily repetition: times / day

Route:

Additional information Comment to the nurse

Instructions: [Modify](#)

Schedule

Administration start: Now Today (8:00 am) Tomorrow (8:00 am)

⚠ No administrations are planned on the first day of this prescription

Repetition (next days): **Repeat every 1 day**

Timeline

1 Tbl at 08:00

14:00 16:19

00:00 03:00 06:00 09:00 12:00 15:00 18:00 21:00 00:00

Thu Aug 08, 2024 : First day of prescription

⚠ No administrations are planned on the first day of this prescription

[Cancel](#) Modification of prescriptions locked for other users Undo Redo [Next](#)

The physician modifies the repetition for the following days: for example every 3 days (instead of every day).

The first administration date is shifted to 3 days from now, instead of remaining scheduled for the following day. This could lead to not administering a drug to a patient until three days after prescription, if it isn't noticed.

Drug prescription*

HOSPITAL Alerts Measured weight 3.375 kg so 0.2195 m²

Prescription Indications Summary

Product(s) & Dose Add a carrier Add a product Add a condition

Drug information - Advice to the physician: Comment AVANT - NEW

Paracetamol 500 mg Tabletten 1 Tbl/take

Daily repetition: 1 times / day Every X hours X times per day Unique PRN

Approx. time Exact time

Route: Oral

Additional information Comment to the nurse

Instructions: Modify

Schedule

Administration start: 11/08/2024 08:00 Now Today (8:00 am) Tomorrow (8:00 am)

Repetition (next days): day week month consecutive alternate Repeat every 3 days

Stop / Pause: No end defined

Timeline

00:00 03:00 06:00 09:00 12:00 15:00 18:00 21:00 00:00

1 Tbl at 08:00

Sun Aug 11, 2024 : First day of prescription

Cancel Modification of prescriptions locked for other users Undo Redo Next →

By backdating the administration start date in the prescription form, it is possible to correct the date of first administration.

Drug prescription*

HOSPITAL Alerts Measured weight 3.375 kg so 0.2195 m²

Prescription Indications Summary

Product(s) & Dose Add a carrier Add a product Add a condition

Drug information - Advice to the physician: Comment AVANT - NEW

Paracetamol 500 mg Tabletten 1 Tbl/take

Daily repetition: 1 times / day Every X hours X times per day Unique PRN

Approx. time Exact time

Route: Oral

Additional information Comment to the nurse

Instructions: Modify

Schedule

Administration start: 09/08/2024 08:00 Now Today (8:00 am) Tomorrow (8:00 am)

Repetition (next days): Repeat every 3 days

Stop / Pause: No end defined

Timeline

00:00 03:00 06:00 09:00 12:00 15:00 18:00 21:00 00:00

1 Tbl at 08:00

Fri Aug 09, 2024 : First day of prescription

Cancel Modification of prescriptions locked for other users Undo Redo Next

This product behaviour, if not detected by the user, might lead to a delay in treatment of the affected patient.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter;
- Release of correction with the update of ORBIS Medication version 03.20 in ORBIS version 84.42 for DACHL (release planned for February 2025);
- Release of correction with the update of ORBIS Medication version 03.20 in ORBIS version 84.42 and 85.25 for FR (release planned for summer 2025).

Recommended actions to be taken by the customer:

- As a physician, always check the first administration date after a modification of repetition (next days).
- Install the correction when available.

Please distribute this information to all those who need to be aware of it.

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:

[<provide contact details>](#)

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: [<provide contact details>](#)
Thank you for your cooperation.

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

Address:

Reference

MST0087678 - The date of the first administration is shifted to a date in the future, instead of being scheduled for the next possible date, if repetition is adjusted.

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: