

23.03.2026

## 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:** Unique Dose administration may be duplicated if the prescription is created in the 24 hours before the change to DST

Internal Reference: MST0099545

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

- ORBIS Medication all versions in Germany, Austria, Switzerland, Luxembourg, France and UK.

Manufacturer: DH Healthcare GmbH

UDI-DI: 4260693990026

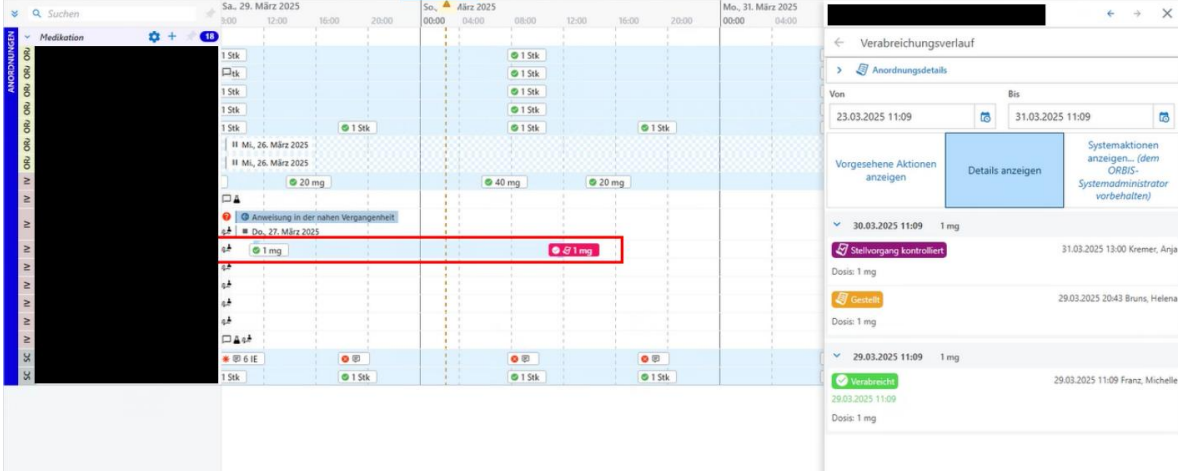
### Information:

The following issue may occur in the Patient Chart only in the context of the daylight saving time (DST) from winter to summer, when a physician prescribes a drug as a unique dose less than 24 hours before changing to daylight saving time (DST). In addition to the scheduled administration of the unique dose, in rare cases, an additional unintended dose may be scheduled for the same time on the following day.

Illustrated scenario:

A physician creates a prescription line as unique dose less than 24 hours before daylight saving time and signs.

Then, in the Patient Chart, another unintended dose may be planned for the following day at the same time in addition to the scheduled one.



If this occurs and remains undetected, it might lead to an additional unintended administration.

## Actions:

### Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Update of the user manual with ORBIS Medication version 03.22.00.00 or higher in ORBIS version 84.44.00.00 or higher (release planned for Q2 2026 for DACHL and Q4 2026 for UK).
- Update of the user manual with ORBIS Medication 03.21.04 or higher in ORBIS version 84.43.02 or higher and 85.26.02 or higher (release planned before the end of Q1 2027 for FR).

### Recommended actions to be taken by the customer:

- We recommend to not use the Unique dose option for an administration scheduled within the 24 hours preceding the switch to daylight saving time during the last weekend of March (March 29<sup>th</sup> of 2026), and to use instead the 1 time per day Daily repetition, by exact time, associated with an end date scheduled before 02:00am the day after.

HOSPITAL [redacted] 80 mg lyoph oral Alerts  Measured weight ? kg so 0 m<sup>2</sup>

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

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Product(s) & Dose

Route: Oral (default route) MA Buccal Other routes

[redacted] 80 mg lyoph oral : 1 gel/take

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

2 3 4 6  times / day Approx. time Exact time

Add a carrier Add a product Add a condition Comment to the nurse Add instruction

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Schedule Reference date: NOW

Repetition (next days): Every day


Administration start: 28/03/2026 02:00 Now Today (2:00 am) Tomorrow (2:00 am)

Stop: No end defined Stop Pause Pause from the start

After 1 day 29/03/2026 01:59 This day only

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Timeline First day of prescription



00:00 03:00 06:00 09:00 12:00 15:00 18:00 21:00 23:59

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Cancel Modification of prescriptions locked for other users Undo Redo Next

- After the release of the version with the updated user manual, please follow the instructions provided in the version of the ORBIS Medication user manual that is applicable to your installation.

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:

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

MST0099545 - Unique Dose administration may be duplicated if the prescription is created in the 24 hours before the change to DST

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: