31-01-2024

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: If a Unique Dose is prescribed between 02:00am and 02:59am the day before the spring time change, another dose is presented the next day

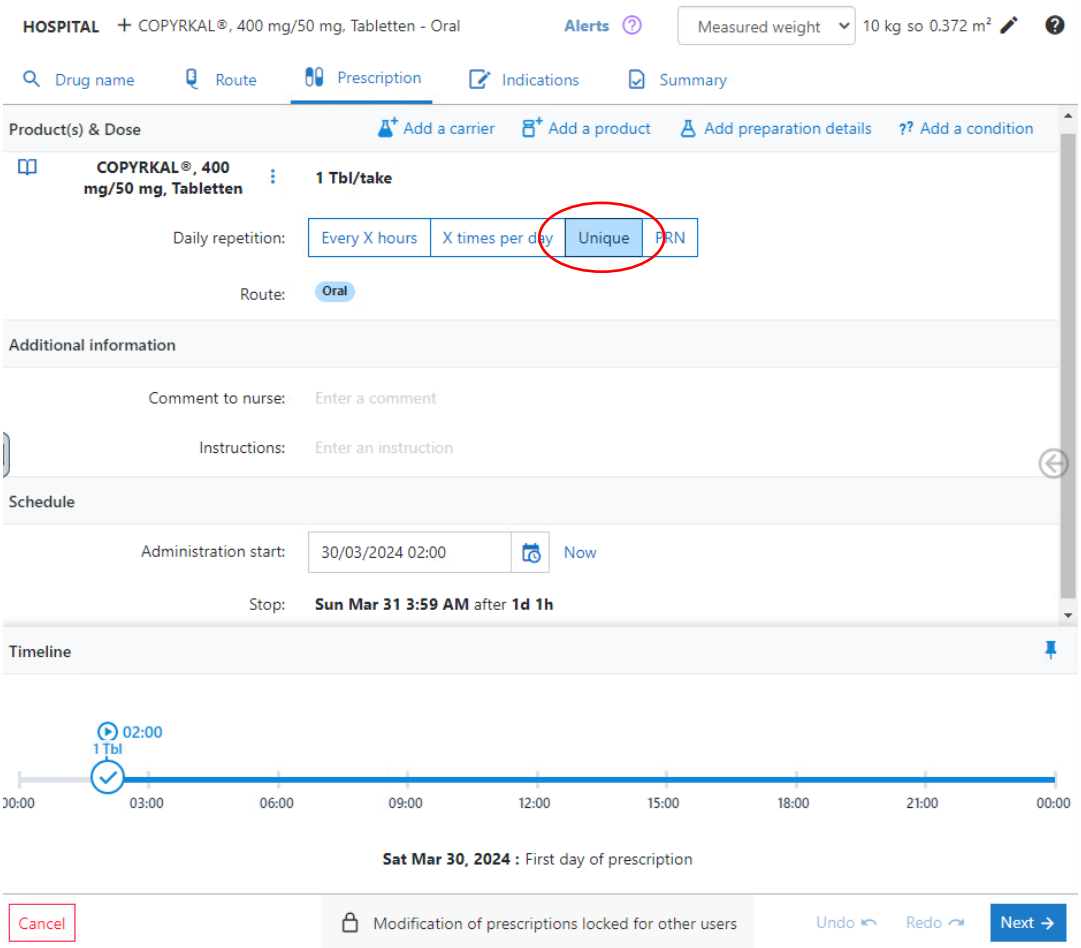
Internal Reference: MST0020202

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

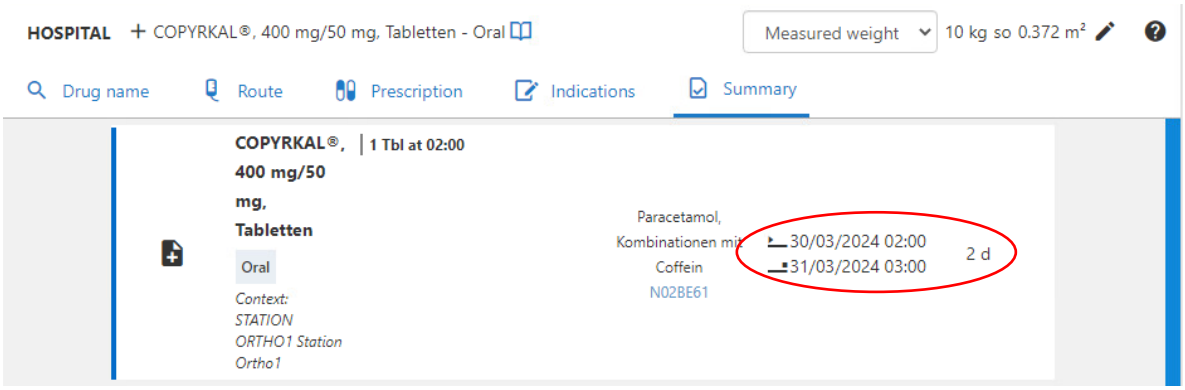
- ORBIS Medication 03.07.00.00 in ORBIS 84.29.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH.
  UDI-DI: 4260693990026.
- ORBIS Medication 03.07.00.00 in ORBIS 85.12.00.00 and higher in France - Manufacturer: DH Healthcare GmbH.
  UDI-DI: 4260693990026.

Information:

The issue occurs in the context of the daylight saving time from winter to summer.
A physician prescribes a drug using the Unique dose option in the 24 hours preceding the switch to daylight saving time (with an administration scheduled between 02:00am and 02:59am the day before) .



A second, unintended administration task, was scheduled the day after the intended unique dose.



Please note that the switch from summer to winter is not affected.

URGENT FIELD SAFETY NOTICE – MST0020202- If a Unique Dose is prescribed between 02:00am and 02:59am the day before the spring time change, another dose is presented the next day

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

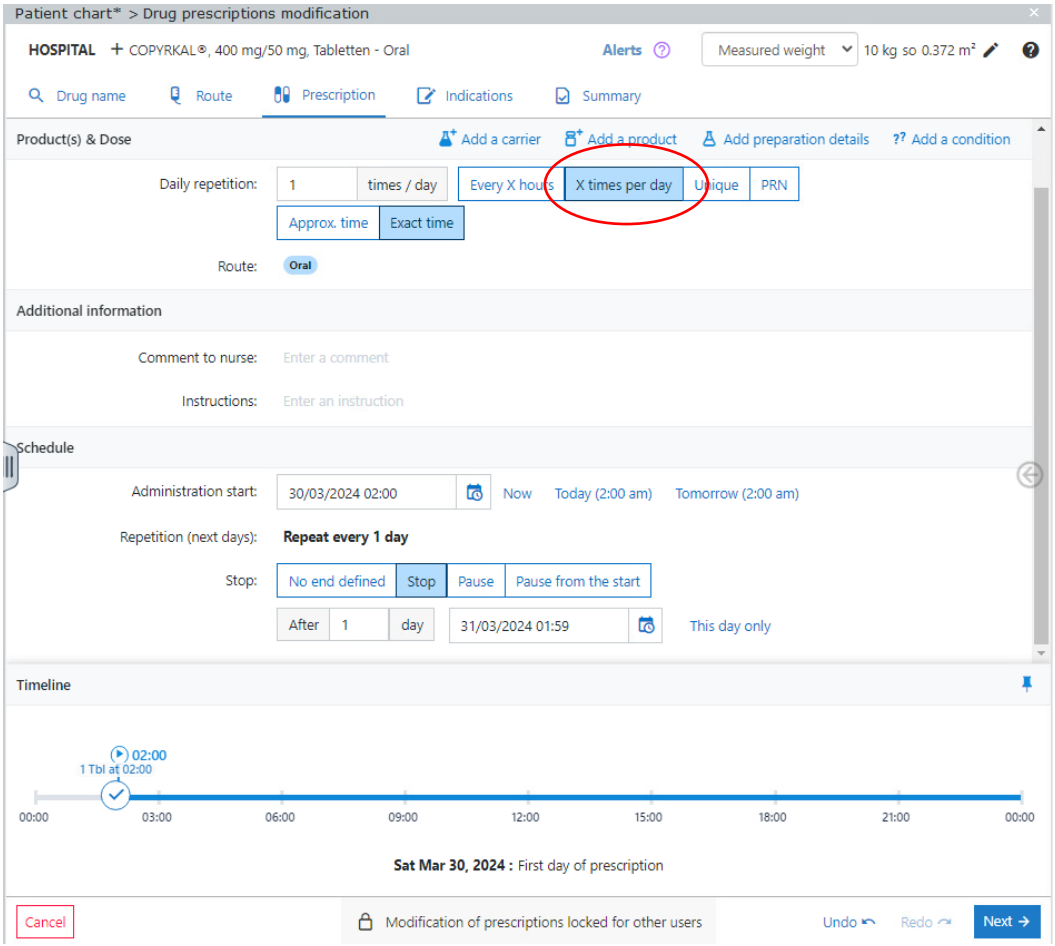
Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication 03.19.02.00 in ORBIS 84.41.02.00.DACHL (release planning: February 2024), 84.41.00.00.FR (release planning: beginning of 2025) and in 85.24.00.00.FR (release planning: February 2024)

Recommended actions to be taken by the customer:

- We recommend to not use the Unique dose option for an administration scheduled between 02:00am and 02:59am the day preceding the switch to daylight saving time, 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.



- Installation of the correction when it is 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:

<Contact Email>

Sincerely,

Name of QARA Director
Title of QARA Director

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: <FeedbackEmail>

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0020202
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: