16-02-2024

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: First administration planned on the following day if the prescription start date is validated few minutes after the planned first administration time

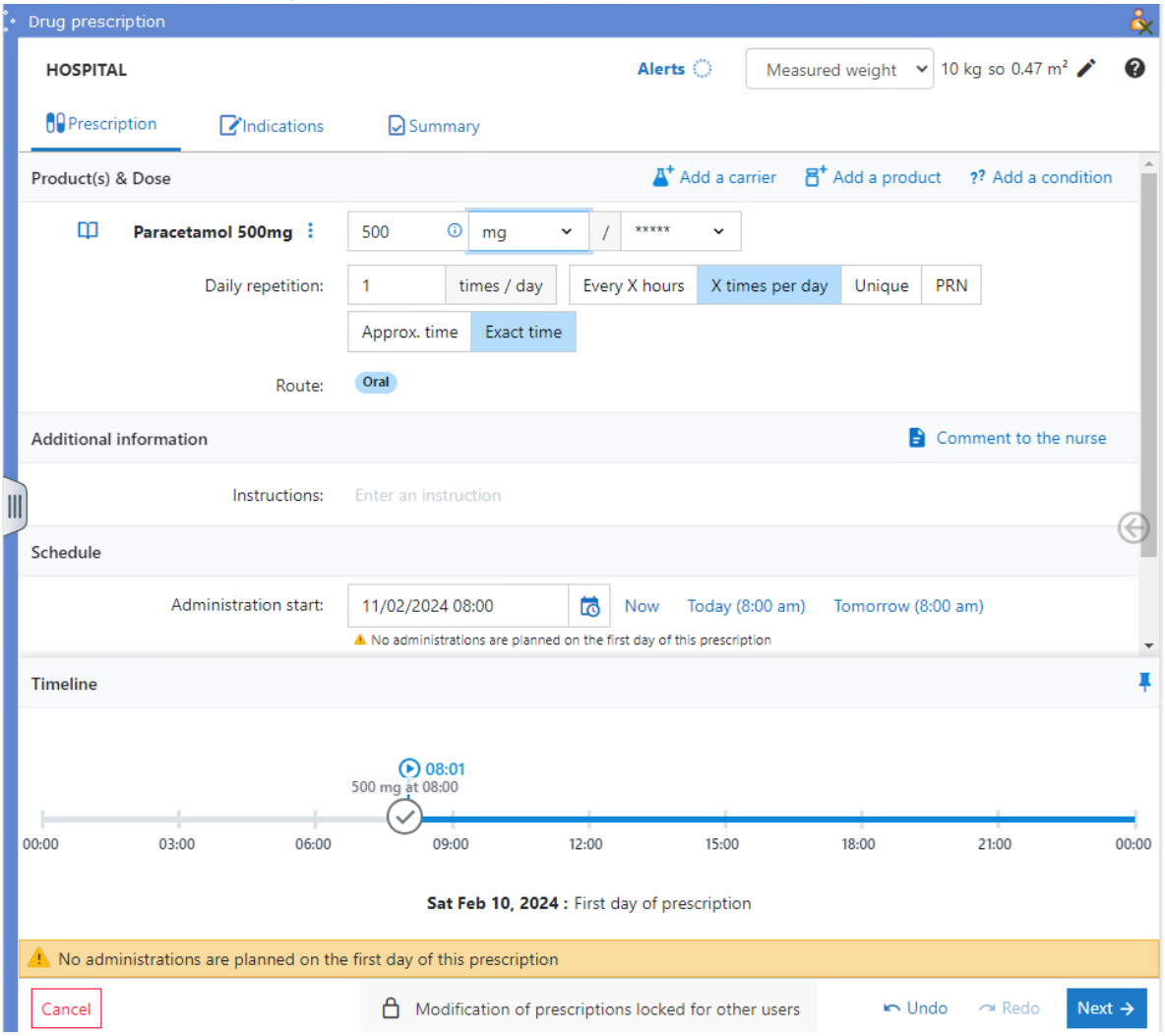
Internal Reference: MST0078556

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

- ORBIS Medication 03.19.00.00 in ORBIS 84.41.00.00. and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
- ORBIS Medication 03.19.00.00 in ORBIS 85.24.00.00. and higher in France - Manufacturer: DH Healthcare GmbH
- UDI-DI: 4260693990026

Information:

A physician modifies the reference date and time of the intended start time for new prescriptions in a patient case, e.g. with a date of February 10 08:00am.
They prescribe a drug scheduled for daily administration at the reference time, e.g. 08:00am.
The first administration is scheduled one day later (i.e. 08:00 on February 11), because the prescription line was only validated after the first administration point in time has already passed.



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 (released on 15.Febr.2024);
- Release of correction with ORBIS Medication 03.19.02.00 in 84.41.00.00.FR & 85.24.00.00.FR (release is planned around last quarter of 2024 but may have to be adjusted depending on the piloting phase).

Recommended actions to be taken by the customer:

- Check the administration start date and modify its value if necessary.
- 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:

<contact email>

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: <contact email>

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0078556 - First administration planned on the following day if the prescription start date is validated few minutes after the planned first administration time
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: