15-02-2024

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: When prescribing from a prescription set, dilutions of products are displayed twice instead of once.

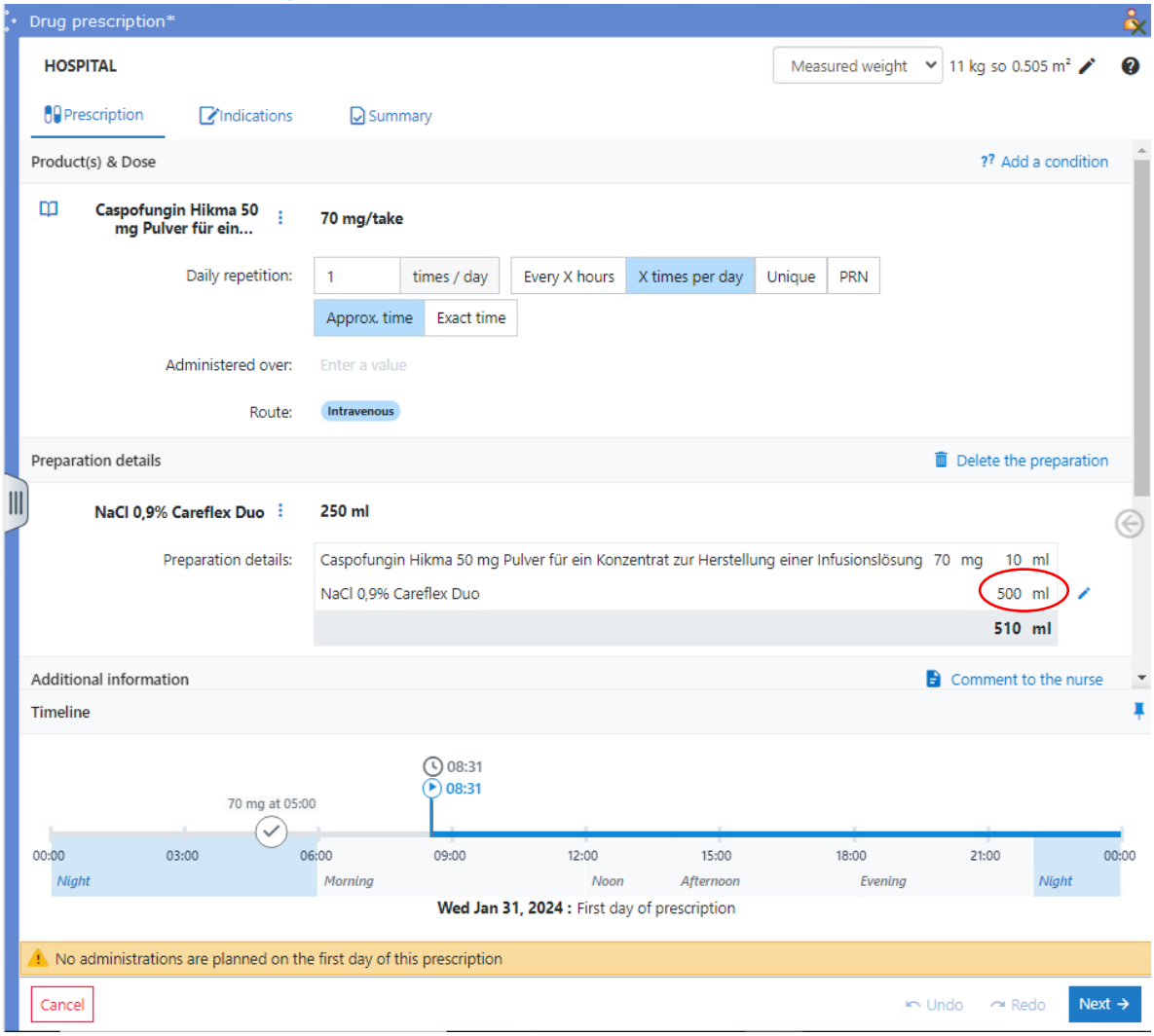
Internal Reference: MST0078354

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

- ORBIS Medication 03.19.00.00 and higher in ORBIS 84.41.00.00 and higher in Germany, Austria, Switzerland, and Luxembourg
  UDI-DI: 4260693990026

Information:

A person in charge of the product configuration defines equivalent units for a product. In the following, we will use "10 ml contain 70mg" to illustrate the behaviour.
A person in charge of the prescription set configuration adds a prescription line with this product.
They configure a daily dose (70 mg), then add a carrier and enter its volume (250 ml), then complete the prescription line.
The preparation details are made of one solution which contains the prescribed dose and the carrier volume together (70 mg in 250 ml of carrier).
When they modify or duplicate the prescription line, a second dilution is automatically added by the system: the preparation instruction suggests two steps of preparation, once with the configured carrier volume (250 ml), and once again with the same carrier volume.
If the person does not realize the issue, the dose is prepared with twice the volume of carrier (500 ml) than was intended.
The same issue occurs at prescription of the prescription set.



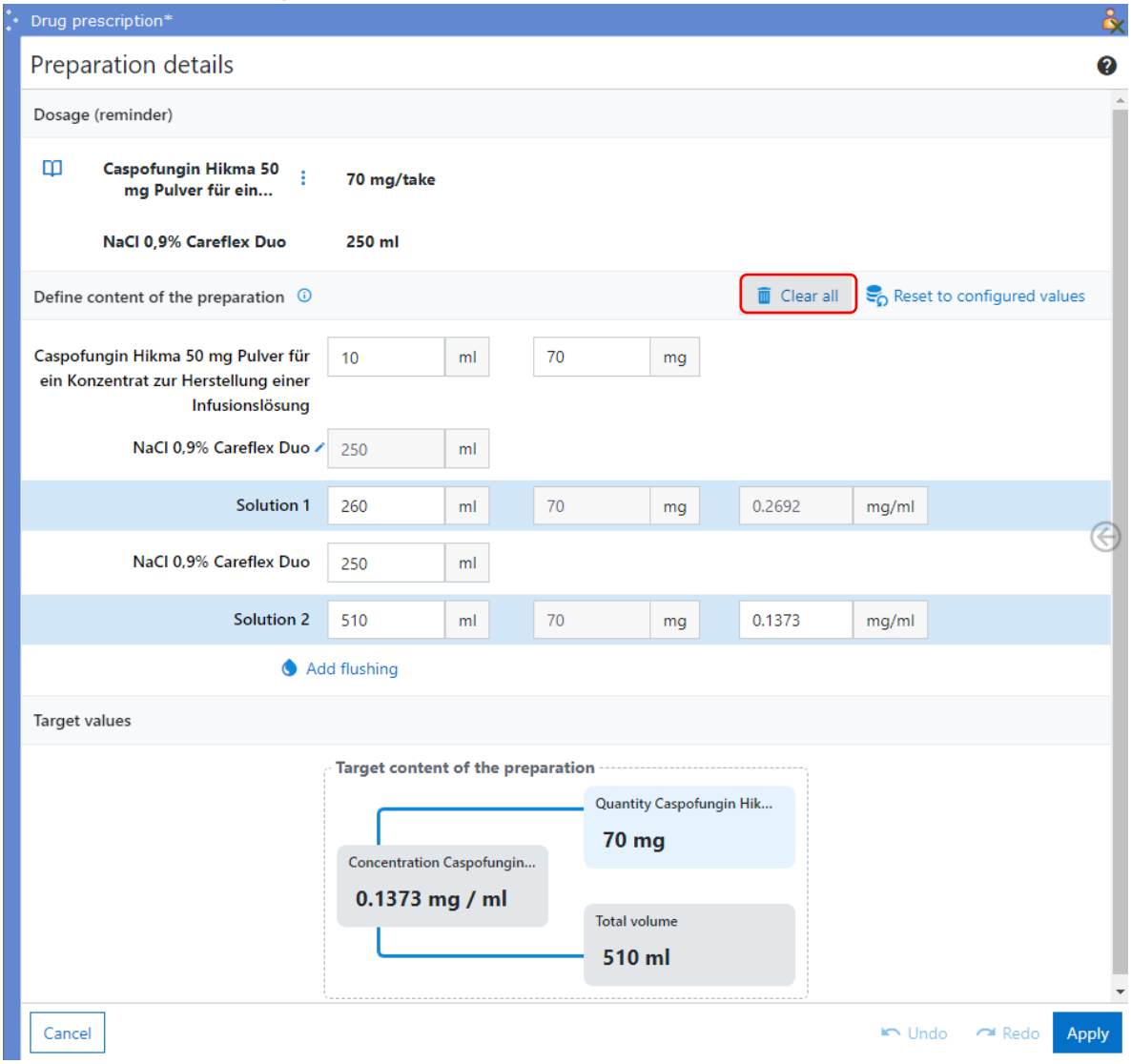
Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.19.02.00 in ORBIS version 84.41.02.00 (released on 15.02.2024).

Recommended actions to be taken by the customer:

- We recommend that physicians check the quantities to be prepared, in addition to the number of resulting solutions, and in the event of too many dilutions, use the **Clear all** action in the **Preparation details** form: this deletes the additional dilution.



- 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:

<provide contact details>

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: <provide contact details>
Thank you for your cooperation.

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

Address: _____

_____

Reference MST0078354

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: