13-06-2024

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: English notification instead of the order condition in requirement/conditional medications

Internal Reference: MST0087039

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

- ORBIS Medication 03.20.00.00 in ORBIS 84.42.00.00 and higher in Germany, Austria, Switzerland and Luxembourg Manufacturer: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

Relevant pre-conditions for the occurrence of this error:
Only customers using the pharmaceutical validation process of prescription lines in ORBIS Medication are affected by this issue.

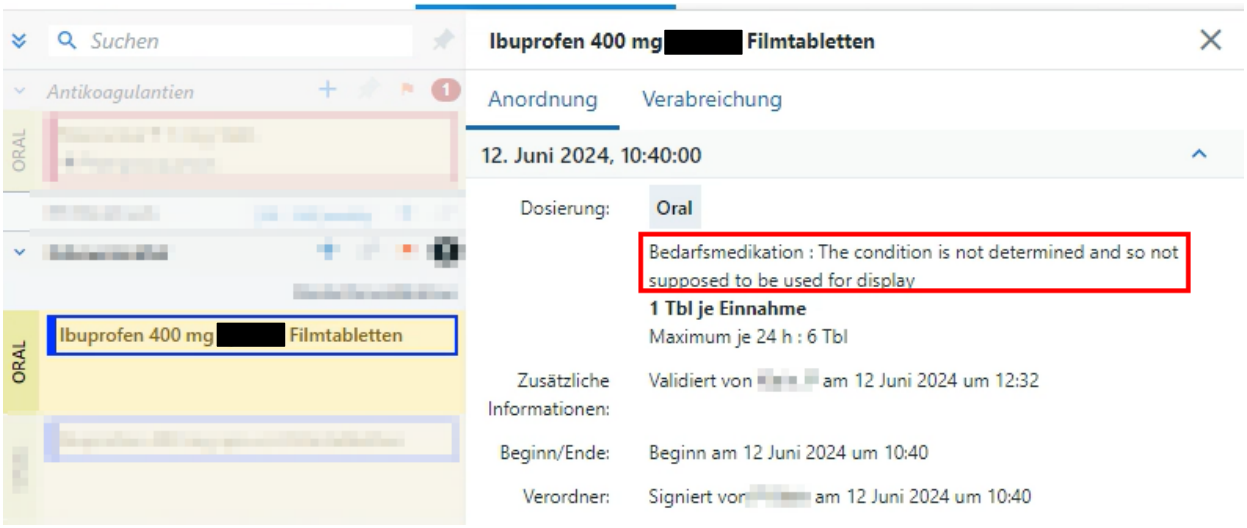
Error description:
After updating to ORBIS Medication version 03.20.00.00 included in ORBIS 84.42.00.00, the following behavior occurs:

In the medication overview, as well as in the Patient Chart (summary section and administration dialog), the text “The condition is not determined and so not supposed to be used for display” is displayed instead of the condition for the prescription line with conditions (e.g. on-demand medication, schema, unknown dosage).

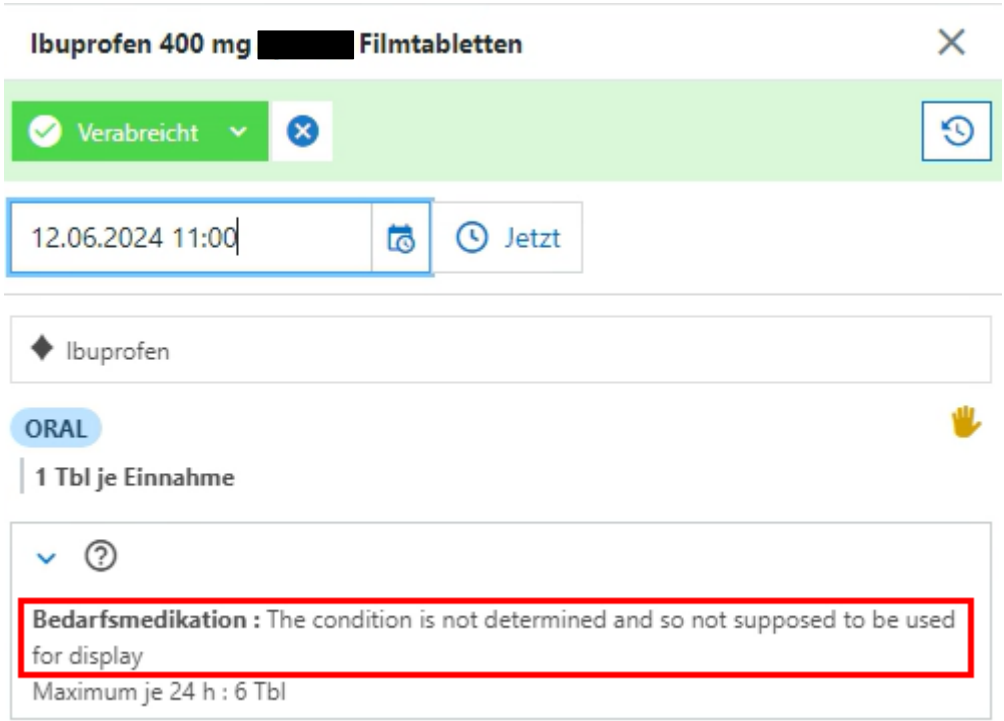
This behavior only occurs if a condition was entered as part of the prescription and the prescription was then signed and validated (e.g. via the Pharmacy Workplace).
As long as the prescription line has not been validated, the display in the medication overview and in the patient chart is correct.

Display of the condition in the medication overview after the validation:

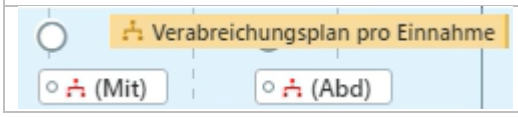
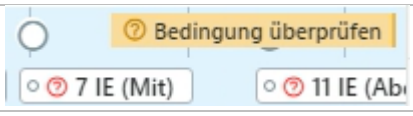
Display of the condition in the summary section of the Patient Chart after the validation:



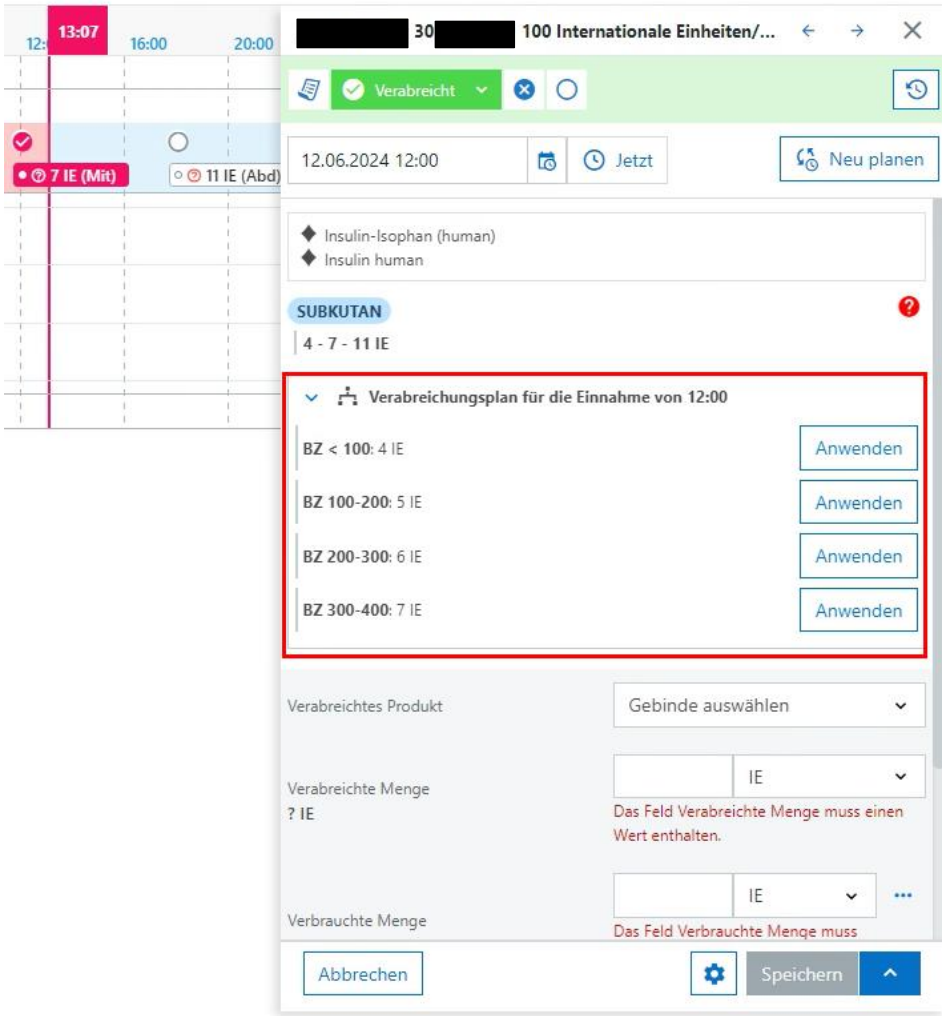
Display of the condition in the administration screen in Patient Chart after the validation:



The display of prescription lines with a schema after validation in the Patient Chart can be misunderstood as dosages to administer by an inattentive user: Instead of the symbol for a schema a dosage is displayed. The marker “conditions to be checked” is still visible on the right side of the screen.

Before validation is done:	After validation is done:
	

The schema is presented correctly when clicking on an administration:



Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the potentially affected customers with this letter.
- Release of correction with ORBIS Medication version 03.20.01.01 and higher in ORBIS version 84.42.01.xx and higher (release planned for July 2024 for DACHL)

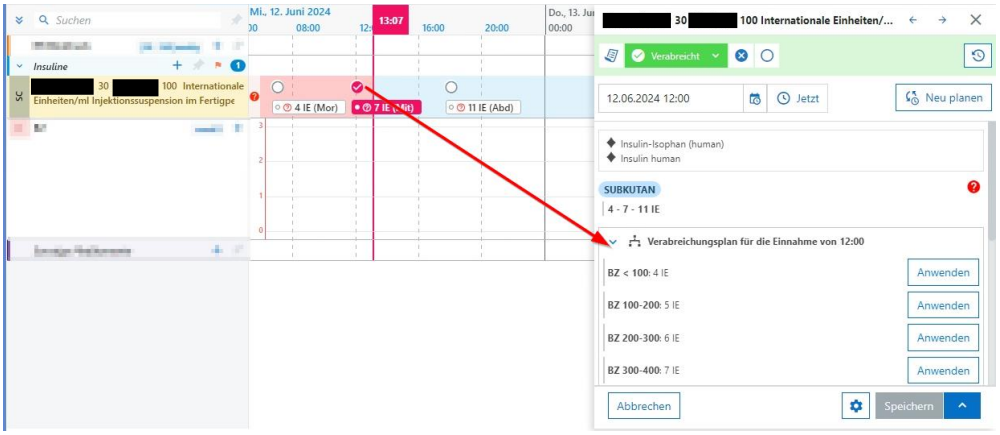
Recommended actions to be taken by the customer:

If the pharmaceutical validation workflow is used in the hospital:

- As a pharmacist when using an affected version: Stop using drug validation for prescriptions with conditions.

- As a physician when using an affected version: Check the active prescription lines of patient cases and change them if an entry in the order summary is incorrect. To do this, you can edit the prescription and sign it again without making any changes. The condition will then be displayed correctly again.

- As a nurse when using an affected version: If the English text “The condition is not determined and so not supposed to be used for display” is displayed for the condition in the order line summary or if other data is not displayed correctly, please contact the physician and ask him/her to edit the line.
  If you are about to administer a drug with a schema, make sure to open the administration and check the schema in the administration view before administering the drug.



- The transfer to the discharge medication and to the discharge letter takes place with the correct representation of the condition.

Please distribute this information to all those who need to be aware of it and confirm the acknowledgement by sending the signed response form.

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,

QARA Director – DH Healthcare GmbH

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	MST0087039: English notification instead of the order condition in requirement/conditional medications
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: