<Date>

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:

Reference: **MST0067975-** ORBIS Medication: Batch number documentation not possible within the Patient Chart (PTC) administration dialogue via the information field.

Product and Product versions

- ORBIS Medication 03.17.00.00 in ORBIS 84.39.00.00 and higher in Germany, Austria, Switzerland, Luxembourg, and France - Manufacturer: DH Healthcare GmbH
- ORBIS Medication 03.17.00.00 in ORBIS 85.22.00.00 and higher in France - Manufacturer: DH Healthcare GmbH

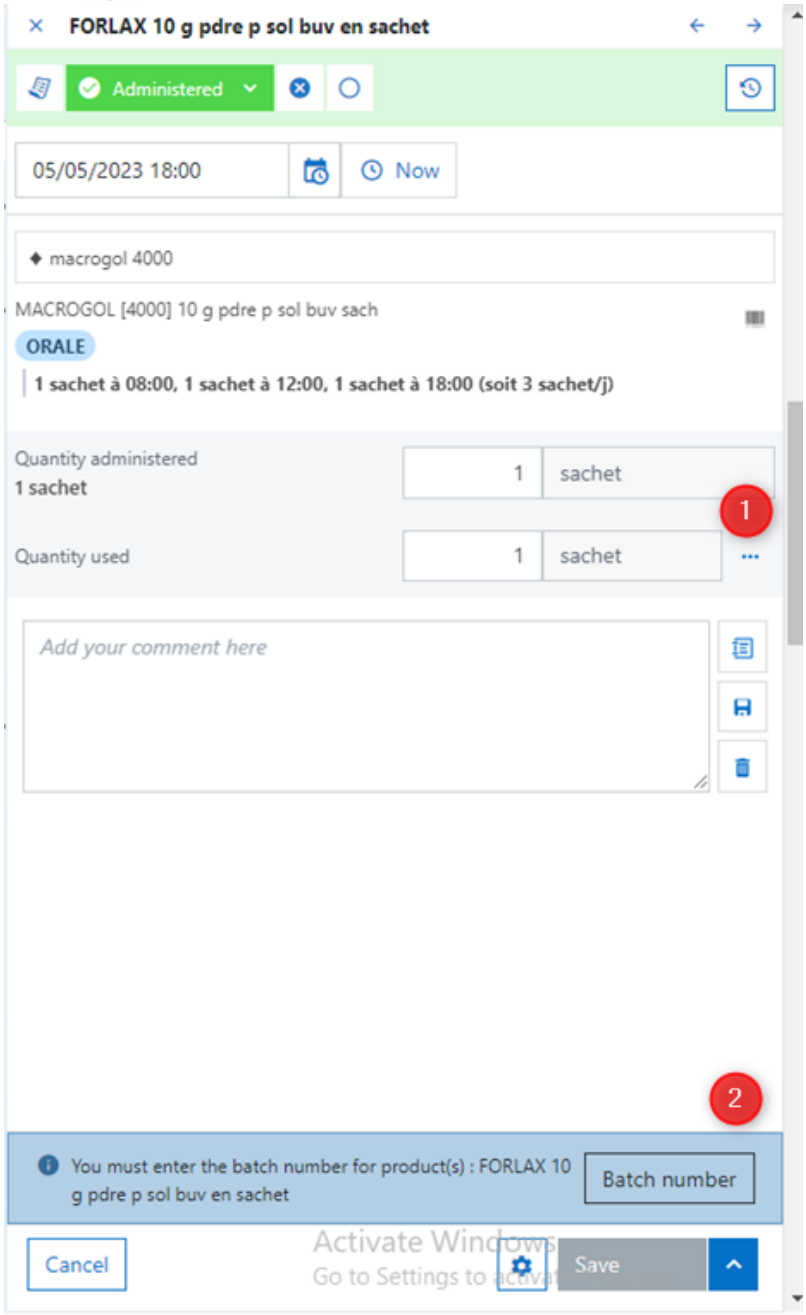
Information:

After update to ORBIS Medication 03.17.00.00 or higher, users have faced the following behavior:

When the batch number of a product is mandatory for administration, i.e. the administration cannot be recorded in the system without this number, the user has two possibilities to fill it in:

The first (1) is the historical option in ORBIS Medication to document a batch number in the administration screen: You must click on the "**three small dots**" button displayed to the right of the quantity used.
The batch number can be entered, and the administration recorded in the system.

The second (2) option is to click on the "**Batch number**" button inserted in the blue alert message. This will take you to the batch number information screen.

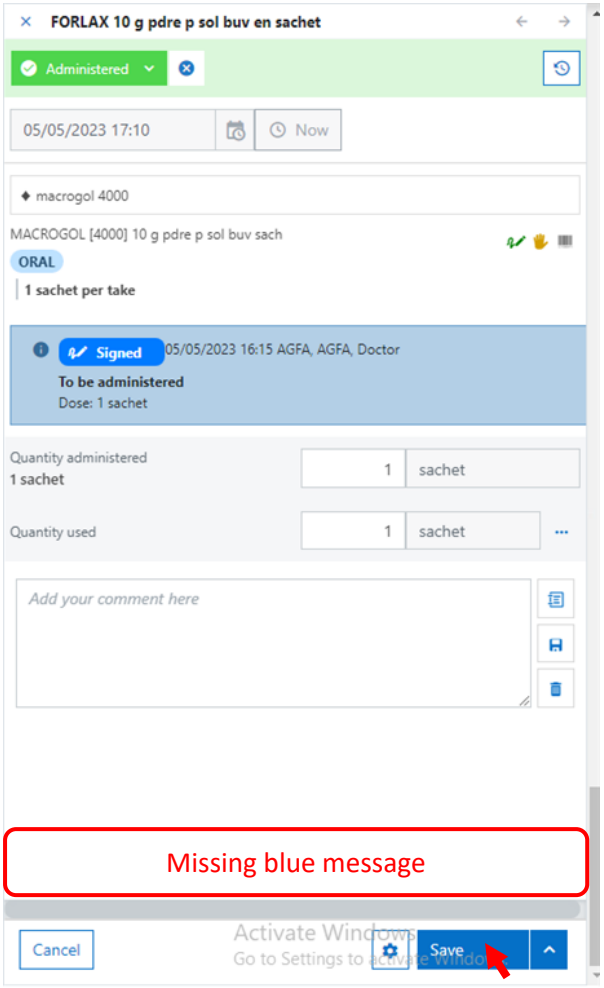


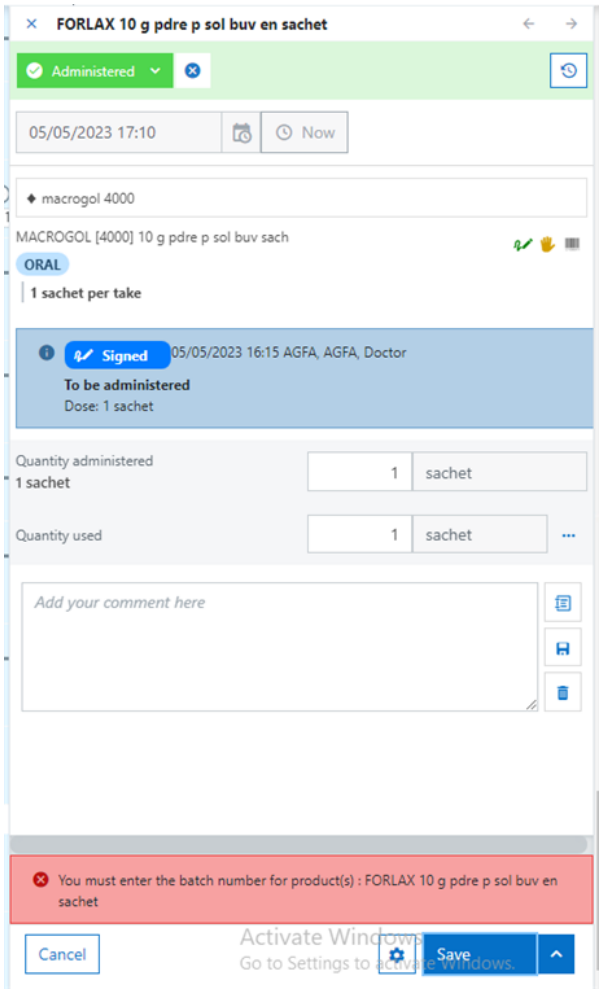
Specifically for cases of a “prescription on demand” (PRN) with Physician's signature and mandatory batch number, there is no blue message requesting the batch number, in the administration screen.

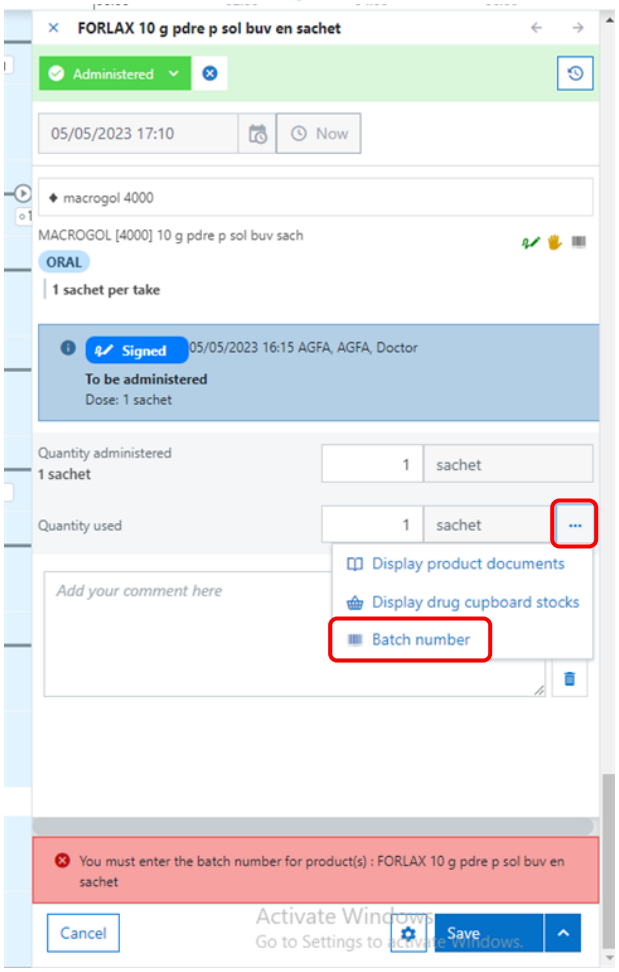
Hence the batch number cannot be entered via the "**Batch number**" button inserted in the blue alert message (option (2)).
However, the batch number can still be recorded using the option (1) clicking on "**three small dots**".

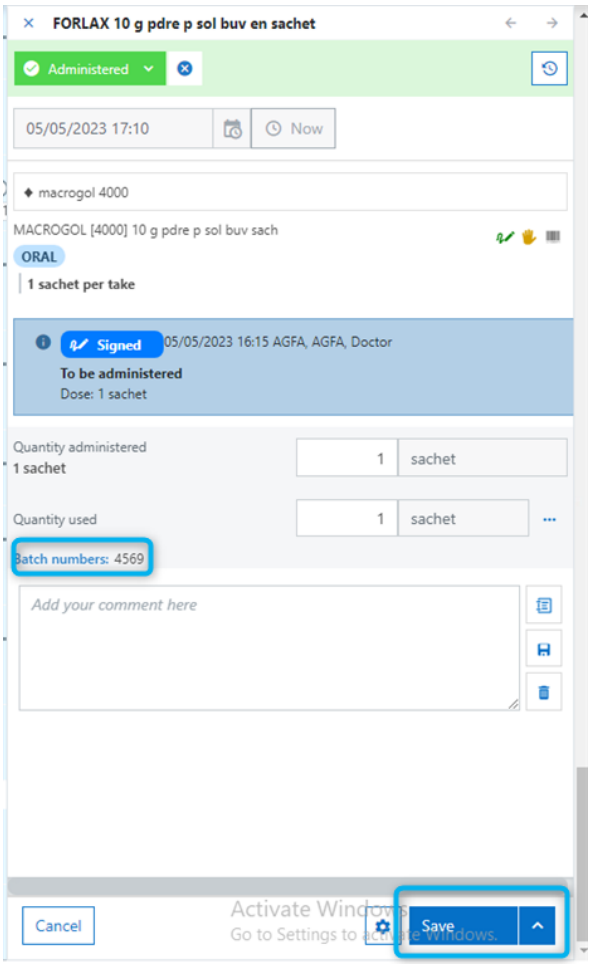
If the user tries to save the administration without entering the batch number, a blocking message asks him to enter the batch number.

For these cases, please use the method described in “option (1)” to document the batch number.









Measures:

Measures by DH Healthcare GmbH

- Inform customers and provision of workaround with this letter.
- Correction will be provided with version
  - ORBIS Medication 03.17.04.00 in ORBIS version ORBIS 84.39.00.01.FR & 85.22.00.01.FR (release planned for August 2023).
  - ORBIS Medication 03.18.01.00 in ORBIS version ORBIS 84.40.01.00.DACHL (release planned for end of June 2023).

Steps to be taken by customers

<u>Before the correction is provided:</u>

- Share this information with all users who might be concerned.
- In case an update to one of the affected versions is planned: ensure that all users are informed – prior to the update - on the working method to document the administration of products with batch number.

Once the correction has been provided:

- Immediately install the provided correction of the software defect.
- Check if the provided correction solves the described behavior. Please contact DH Healthcare GmbH in case you need support.

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>

L'équipe Support
<contact>

Kind regards,

<Signature>

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>**

Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0067975
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: