

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) .

HOSPITAL + COPYRKAL®, 400 mg/50 mg, Tabletten - Oral Alerts ? Measured weight 10 kg so 0.372 m² ?

[Drug name](#) [Route](#) [Prescription](#) [Indications](#) [Summary](#)

Product(s) & Dose + Add a carrier + Add a product + Add preparation details ?? Add a condition

COPYRKAL®, 400 mg/50 mg, Tabletten 1 Tbl/take

Daily repetition: Every X hours X times per day **Unique** PRN

Route: **Oral**

Additional information

Comment to nurse:


Instructions:

Schedule

Administration start: Now

Stop: **Sun Mar 31 3:59 AM after 1d 1h**

Timeline



Sat Mar 30, 2024 : First day of prescription

Cancel Modification of prescriptions locked for other users Undo Redo Next →

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

HOSPITAL + COPYRKAL®, 400 mg/50 mg, Tabletten - Oral Measured weight 10 kg so 0.372 m² ?

[Drug name](#) [Route](#) [Prescription](#) [Indications](#) [Summary](#)

COPYRKAL®, 400 mg/50 mg, Tabletten 1 Tbl at 02:00

Oral

Context: STATION ORTHO1 Station Ortho1

Paracetamol, Kombinationen mit Coffein N02BE61

30/03/2024 02:00 31/03/2024 03:00 2 d

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

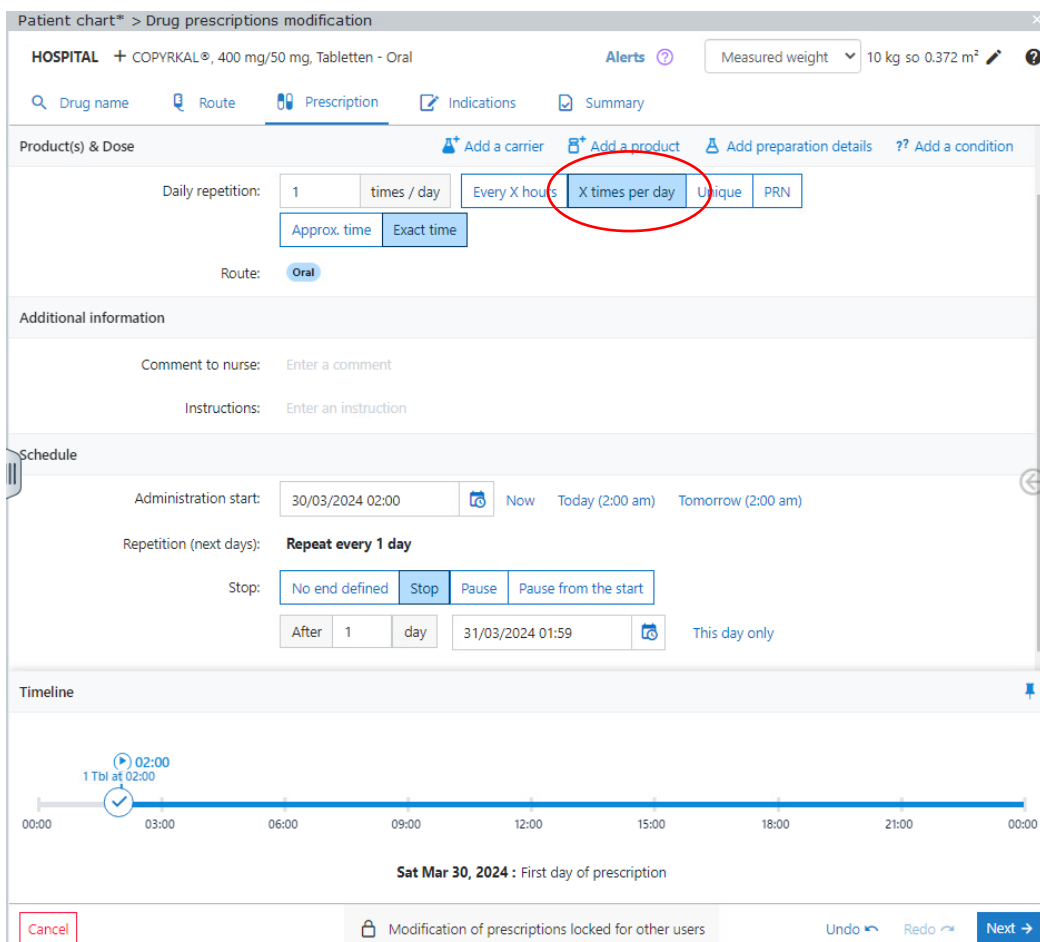
Actions:

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.



Patient chart* > Drug prescriptions modification

HOSPITAL + COPYRKAL®, 400 mg/50 mg, Tabletten - Oral Alerts Measured weight 10 kg so 0.372 m²

Drug name Route Prescription Indications Summary

Product(s) & Dose Add a carrier Add a product Add preparation details Add a condition

Daily repetition: 1 times / day Every X hours X times per day Unique PRN

Approx. time Exact time

Route: Oral

Additional information

Comment to nurse: Enter a comment

Instructions: Enter an instruction

Schedule

Administration start: 30/03/2024 02:00 Now Today (2:00 am) Tomorrow (2:00 am)

Repetition (next days): Repeat every 1 day

Stop: No end defined Stop Pause Pause from the start

After 1 day 31/03/2024 01:59 This day only

Timeline

1 Tbl at 02:00

Sat Mar 30, 2024 : First day of prescription

Cancel Modification of prescriptions locked for other users Undo Redo Next

- 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: