
Urgent safety information

Voluntary recall

concerning

epicite^{hydro}

Jena, 29.02.2024

Dear customer!

With this letter we would like to inform you that the JeNaCell GmbH, Göschwitzer Str.22, 07745 Jena, as the responsible manufacturer voluntarily carries out a recall regarding the products listed below.

It concerns the wound dressing epicite^{hydro} for use in first and second degree burns;

<u>article</u>	<u>Ref no.</u>	<u>content (pc)</u>	<u>LOT Number</u>	<u>Expiry date</u>
epicite ^{hydro} 10x10	800003-M02B	10	220820	2025-08-31

JeNaCell GmbH has received feedback regarding a product. The packaging is suspected of leaking. This is the first notification since the product batch was placed on the market in October 2022. Some packaging in the listed batch could possibly be manufactured with a faulty seal. There may be a health risk from contamination due to a leaky seal of the sterilisation packaging. The probability of a non-sterile wound dressing is very low. JeNaCell GmbH has not received any reports of incidents related to the impairment of sterility.

Using a non-sterile product can expose patients to infectious agents and increase the risk of infection. The probability of an unsterile dressing is low. JeNaCell GmbH has received no reports of incidents in connection with the impairment of sterility. In the course of our investigations and risk assessment we have decided to withdraw the affected products from the market as a precautionary measure.

Notes on the measures to be taken by the user:

1. please immediately examine your inventory of all batches subject to this voluntary recall

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If you have resold these products, you must identify your customers and notify them of this voluntary product recall. All potential users of these products in your customer supply chain must be considered. Please send them a copy of this safety notification.

2. please complete the attached Appendix 1: Reply form IMMEDIATELY as proof of product return, OR fill in the reply form even if you do not have any have products in your inventory.

3. send attachment 1: Reply form to JeNaCell GmbH by e-mail to stephanie.fritsche@evonik.com

4. send ALL quarantined products from the affected batches back to our company by 31. 01. 2020 at the latest by contacting JeNaCell GmbH at the following telephone number
TEL.: +49 3641-2350114

Please keep this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this "Urgent Safety Information".

We thank you for your understanding and apologize for any inconvenience this may cause.

With kind regards,

Christin Stäffel
PRRC

Annex 1 - Reply form

JeNaCell GmbH epicitehydro wound dressing for first and second degree burns

Please fill in this reply form and send it
by 15.03.2024 at the latest.

Please check the corresponding answers.

STEP 1: Check your inventory for

<u>article</u>	<u>Ref no.</u>	<u>content (pc)</u>	<u>LOT Number</u>	<u>Expiry date</u>
epicite ^{hydro} 10x10	800003-M02B	10	220820	2025-08-31

Please tick ALL applicable boxes.

- I have read and understood the recall instructions in the letter dated December 19, 2019
- I have identified and notified my customers that products affected by this voluntary recall have been shipped to them.

(indicate date and type of notification);

I have checked my inventory and have no affected units in my inventory.

I have checked my stock and quarantined the following inventory:

<u>article</u>	<u>Ref no.</u>	<u>content</u> <u>(pc)</u>	<u>LOT Number</u>	<u>Expiry date</u>	<u>amount</u>
epicite ^{hydro} 10x10	800003-M02B	10	220820	2025-08-31	

STEP 2: To be filled in by the recipient:

your name: _____

titel: _____

telefonnummer: _____

name of the company: _____

E-Mail: _____

address: _____

city / state / canton: _____

STEP 3: Return form

Please send this completed reply form by 30 December 2019 by e-mail to

Stephanie.fritsche@evonik.com

***** *Many thanks for your support in this matter* *****