

Urgent safety information

Optional recall

concerning

epicite ^{hydro}

Jena, 19.12.2019

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;

article	ref no.	content (pc)	batch number	expiry date
epicite ^{hydro} 10x10	800003-M02B	10	190415	2022-04-30
epicite ^{hydro} 10x10	800003-M02B	10	190839	2022-08-31
epicite ^{hydro} 15x20	800003-M06B	10	190416	2022-04-30
epicite ^{hydro} 15x20	800003-M06B	10	190840	2022-08-31
epicite ^{hydro} 20x20	800003-M09A	5	190417	2022-04-30
epicite ^{hydro} 20x20	800003-M09A	5	190841	2022-08-31
epicite ^{hydro} face	800003-M010A	5	190418	2022-04-30
epicite ^{hydro} face	800003-M010A	5	190842	2022-08-31



During the sterilization validation process, there were some anomalies regarding the sterility of the products. 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 actions to be taken by the user:

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

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epicite ^{hydro} 10x10	800003-M02B	10	190415	2022-04-30
epicite ^{hydro} 10x10	800003-M02B	10	190839	2022-08-31
epicite ^{hydro} 15x20	800003-M06B	10	190416	2022-04-30
epicite ^{hydro} 15x20	800003-M06B	10	190840	2022-08-31
epicite ^{hydro} 20x20	800003-M09A	5	190417	2022-04-30
epicite ^{hydro} 20x20	800003-M09A	5	190841	2022-08-31
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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 fill out the enclosed appendix1: Reply form IMMEDIATELY as proof for the product return, OR fill out the reply form even if you do not have any products in your inventory to be returned.

3. send appendix 1: Reply form to JeNaCell GmbH by e-mail to



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 3641-508460

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,

Appendix 1 - Reply form

JeNaCell GmbH epicite^{hydro} wound dressing for first and second degree burns

Please fill in this reply form and send it

by 30 December 2019 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>batch number</u>	<u>expiry date</u>
epicite ^{hydro} 10x10	800003-M02B	10	190415	2022-04-30
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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>batch number</u>	<u>expiry date</u>	<u>amount</u>
epicite ^{hydro} 10x10	800003-M02B	10	190415	2022-04-30	
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epicite ^{hydro} face	800003- M010A	5	190842	2022-08-31	



STEP 2: to be filled in by the recipient:

your name: _____

titel: _____

telephone number: _____

name of the company: _____

E-Mail: _____

address: _____

city / state / canton: _____

STEP 3: Reply form

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

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