
Urgent Safety Notice

Batch recall

concerning

Cathejell Lidocain C
Batch concerned: 26741

2022-11-XX

Sender:

Pharmazeutische Fabrik Montavit GmbH
Salzbergstraße 96
6067 Absam
Austria
Phone: +43 5223 57926
E-mail: pharma@montavit.com

Addressee:

Pharmacies, hospital pharmacies, pharmaceutical wholesalers

Identification of the concerned medical device:

Product Category/GMDN	Sterile lubricant/60796 – General-body orifice lubricant, sterile
Trade name	Cathejell Lidocain C
PZN	07094085
Catalogue number	400151
Batch/batch number	26741
Manufacturing date	2022-01-14
Expiry date	2024-12-31

Description of the problem, including the identified cause:

As part of ongoing stability reviews, batch 26741 of Cathejell Lidocain C was found to deviate from the valid specification in the chlorhexidine content. Therefore, the concerned batch of the medical device Cathejell Lidocaine C is recalled at wholesale and pharmacy level as a preventive measure. Other batches are not affected by this recall in Germany. There is no acute risk to the health of the patients.



What measures are to be taken by the addressee?

We kindly ask you to check your stock levels and return all packages of the mentioned batch to us by XX.12.2022 using the attached form with sufficient postage. Based on this, we will make a refund including a postage fee (10€).

Disclosure of the information described here:

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are aware of this Urgent Safety Notice. If you have given the products to third parties, please forward a copy of this information or inform the contact person below.

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

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

Contact:

Questions about the recall

Dr. Pflieger Arzneimittel GmbH

Customer service team by e-mail to ksc@dr-pfleger.de or

under +49 951 6043-799

Dr.-Robert-Pfleger-Str. 12

96052 Bamberg

Germany

Questions about the background of the recall

Pharmazeutische Fabrik Montavit GmbH

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6067 Absam

Austria

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E-mail: pharma@montavit.com

██████████
Head QA Medical Devices / QMB / PRRC / Qualified Person

Pharmazeutische Fabrik Montavit GmbH

Return form Cathejell Lidocain C

Batch: 26741

End of action: XX December 2022

Batches and quantity concerned:

PZN	Pack size	Batch	Expiry date	Quantity	Comment
07094085	8.5 g 25 pcs	26741	12/2024		

Please note that only the medical device listed here should be returned.

Statement:

- We confirm that the goods listed here and returned have been properly stored since delivery, in particular they have not left the area of responsibility of the pharmacy / wholesale warehouse.

Company / pharmacy name	
Owner	
Address	
Customer number	

Stamp with date and signature:

Place, date _____ Signature _____

Return to:
 Dr. Pflieger Arzneimittel GmbH
 - Returns department
 Dr.-Robert-Pfleger-Str. 12
 96052 Bamberg

Contact for queries:
 Customer Service Team by e-mail
 to ksc@dr-pfleger.de or
 under the number
 +49 951 6043-799