

Urgent Field Safety Notice

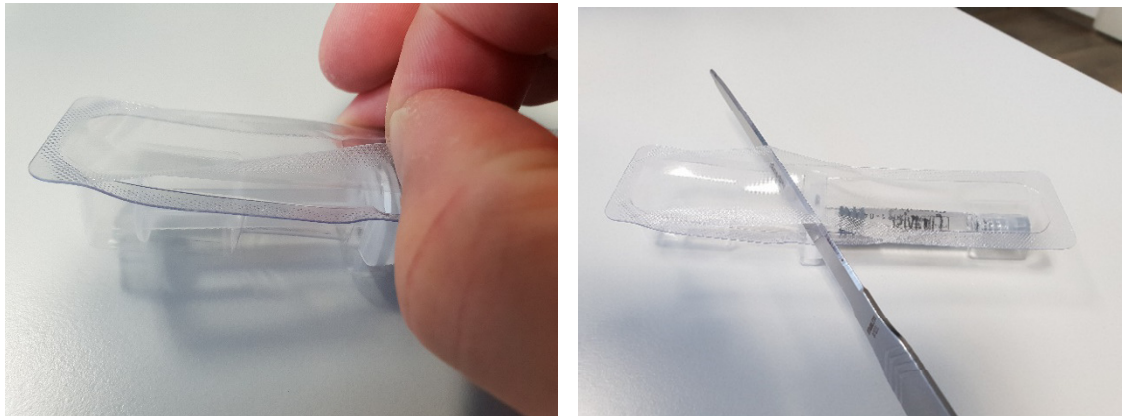
Product: Curavisc®, Hyaluronic Acid 1%
Lot number: Chargennummer 1807781
FSCA Number: FSCA Number BfArM
Required action: Disposal of syringes in untight blister packaging

Dear Customer,

We would like to inform you that our delivery of **Curavisc®**, Hyaluronic Acid 1%, **Lot 1807781 of (Date)**, may contain products with untight blister packaging as shown in the pictures below and which was reported to us by a customer.

Description of issue:

Untight blister packaging, Curavisc®, Lot no.1807781



Although the sterility of the Curavisc® syringe with the 1% hyaluronic acid is not affected, we cannot rule out the possibility that due to the leakage the inside of the blister packaging contains impurities that are undesirable in the application environment.

Required actions:

We ask you to check the blister packages for leaks before Curavisc® is used and destroy and not use syringes delivered in leaking packaging.

Please fill out the confirmation form next and send it to the following contact:

Curasan AG
Attn. Mr Florian Fröh
Fax +49 6027 40900 149

Email: florian.frueh@curasan.com

In doing so, you confirm the receipt of the Field Safety Notice and the implementation of the measures. A replacement for incorrectly packaged Curavisc ® is only possible after appropriate feedback.

Forwarding of this Field Safety Notice:

This notice must be forwarded to anyone involved in your organization or other organizations who should know about it, are affected, or to whom you have delivered products from the Curavisc ®, Hyaluronic Acid 1%, batches number 1807781.

If you still use products from other batches, you may find the batch number also on the packaging (pictured) for separation of the product.

The relevant authority in Germany has been informed of this Field Safety Corrective Action.

We apologize for any inconvenience caused to you or has already arisen and still hope for a good cooperation.

Kind regards,

ppa Head of Marketing

i.v. Product manager

Customer confirmation sheet

Please fill out the form and send it immediately to:

Curasan AG
Lindigstrasse 4
63801 Kleinostheim ,
Attn Mr Florian Fröh
Fax +49 6027 40900 149
Email: florian.frueh@curasan.com

Product:	Curavisc®, Hyaluronic Acid 1%,
Product number:	9210 000 001
Lot number:	1807781
FSCA number:	K 191801 R
Date:	
Required action:	Disposal of syringes in defective secondary packaging

Our records show that you received the following affected products:

Number:

Order from:

To be confirmed by the Physician:

_____ I have received the urgent Field Safety Notice regarding
Curavisc® Hyaluronic Acid 1%, Lot number 1807781

_____ I checked delivery for faulty secondary packaging

_____ Number of faulty secondary packaging has been found and disposed of.

Please provide a picture of the affected product for further internal root cause analysis.

Place, date

Name,

Signature

Institution

Department

Address

Phone

Fax

Email

For cursan AG internal use only

Received on

Signature