

URGENT Field Safety Notice

HealafLOW

Details on the affected medical devices:

HEALAFLOW is an injectable filtering spacer consisting of highly cross-linked hyaluronic acid, isotonic and sterile presented in a glass syringe. It may be applied to preserve the filtration function in the postoperative period of glaucoma surgery of adults by maintaining the volume of the subconjunctival filtration space (filtering bleb). Syringe of HealafLOW gel is supplied with a needle. They are packed separately.

Description of the problem:

Expiry date of the needle inside the box is 2020-11 however the box of HealafLOW expiry date is 2021-03. The use of the needle may present a sterility risk if used between 2020-11 and 2021-03.

Actions taken by the manufacturer:

A tracking of all the products from batch 341335/1 is organized by Aptissen as well as spread out of this Field Safety Notice.

An investigation is in process.

Actions required from users:

- Verify your stocks and the stock of your customers and identify if you or they are still in possession of HealafLOW from batch 341335/1. This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact.
- Put those references in quarantine or ask your customer to put them in quarantine and ensure that they are not used anymore.
- Complete and sign the below formular. Send it back to support@aptissen.com,

Contact of the person in charge at Aptissen:

For more information, please contact Marylise ROBERT by email at m.robert@aptissen.com or by post at the following address:

Aptissen SA
Chemin du Champ des Filles 36A
1228 Plan Les Ouates
Switzerland

Reply form

Please send this form back to Aptissen at support@aptissen.com or by post at the following address:

Aptissen SA
Chemin du Champ des Filles 36A
1228 Plan Les Ouates
Switzerland

I acknowledge the receipt of this Field Safety Notice from Aptissen SA, related to Healaflow batch 341335-1 products and I verified my stock and the stock of my clients.

The following products are still in stock and are put in quarantine either in my location or at my client's location:

Reference	Quantity of products*
Healaflow Batch 341335/1	

*if no products has been found in stock, put NA.

Company name	
Name of the person in charge	
Position of the person in charge	
Date	
Stamp & Signature	