Urgent Field Safety Notice

042.001 Hydraclair Ampoules
Withdrawal

Date: Uden, 04 August 2020

Attention: [redacted]

Details on affected devices:
Herewith, we inform you of the withdrawal of 042.001 Hydraclair Ampoules (classified as a Class IIb device) which is manufactured [as the legal manufacturer per MDD 93/42 EEC] by Barnaux Healthcare. The notice covers lot number Y351C and is applicable for all European countries where this product has been marketed. It has been marketed under several brand names, the brand(s) that you have purchased are:

Transaction Date	CO Number	Item Number	Item Description	Lot Number	Shipped Quantity
23-apr-20	200320-023	QEY08007	EYEYE HYDRACLAIR AMPUL WEST	Y351C	192

Description of the problem:
The manufacturer was informed by an eye specialist about an unexpected adverse effect of a mild dilated pupil after instilling the 042.001 Eye drop, batch Y351C. We initiated a root cause investigation together with the external supplier of the single use preservative free eye drops.

As a result of this investigation we concluded that the Eye drops 042.001, batch Y351C had been contaminated with a low concentration of the pharmaceutical substance tropicamide. Tropicamide is a well-known mydriatic and cycloplegic agent used to enlarge the pupils for an eye examination by an eye specialist. The cross-contamination is limited to the batch concerned and appropriate corrective and preventive actions have been implemented by the external supplier to prevent further cross-contamination.

The external subcontractor concluded that remnants of the medicine containing tropicamide remained in the compound vessel used for the preparation of batch Y351C. The concentration of tropicamide varies within the batch and is strongly diluted. The highest concentration measured in the retention samples are found at the initial start-up of the batch, a concentration of 0.065% w/v of the pharmaceutical substance is found in the 042.001 Eye drop, while the original dosage of the diagnostic medicine tropicamide is 1%. The retention samples taken from the middle and the end of the batch contained a concentration of 0.0035% w/v tropicamide. We concluded that the lowest concentrations tropicamide found in the middle and at the end of the batch does not cause an adverse effect or a reaction of the pupil. The higher concentrations tropicamide could cause an acute

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adverse reaction of the pupil causing temporary sensitivity to light or blurred vision as a side effect caused by the dilated pupil.

We determined that the potential health risk for users of the Eye drops, batch Y351C, is very low and highly unlikely to cause a serious deterioration in health. The potential adverse effects are limited to irritation due to tropicamide sensitivity, temporarily light sensitivity and blurred vision. The warning in the instructions for use of the 042.001 Eye drops describe in case of irritation to discontinue use of the Eye drops and to contact an Eye specialist.

Suggested action to be taken:
The steps to be taken in order to return the affected products to Barnaux Healthcare are defined as follows:

- Confirm the receipt of this field safety notice as soon as possible but not later than 06 August 2020;
- Identify and quarantine all the products in stock mentioned above; and,
- Inform Barnaux Healthcare on the number of products: 042.001 Eye drop, batch Y351C that you have in your possession;
- Complete the confirmation form attached to this letter and return it to Oté by email before August 14th latest by sending it to **backoffice@ote.nl**;
- Oté will arrange logistics for this shipment back to Oté.

Transmission of this Field Safety Notice
This notice needs to be passed on to all those who need to be aware within your organization or to any other organization where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

We sincerely offer you our apologies for the inconvenience caused by this measure.

Kind regards,
Barnaux Healthcare B.V.

Rob Oorthuizen / Jorn van Hoevelaak
Vluchtoord 38 5406 XP Uden, The Netherlands

Please contact our Back Office for any question
+31 (0)413 24 10 16

Confidential agreement: the information supplied in this letter should be treated confidentially as it is only intended for the addressee of this letter. In case you are not the appropriate person, nor responsible agent for this reseller, we would like you to take notice of the fact that release of any information in this letter is strictly forbidden. Please contact us directly, if you received this letter unintendedly to arrange the return of the original documentation.

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Confirmation form corresponding to recall of the 042.001 Hydraclair Ampoules

(please add a copy of this form to the products to be returned)

Details of the **042.001 Hydraclair Ampoules**

This form is to confirm that you have received the notification letter for the withdrawal which is initiated as a precautionary measure, dated 04 August 2020.

Please indicate the option that represents your situation best:

☐ **Possess the following products to be returned**

Please confirm the amount of stock in your asset by completing the table below.

Product name	Article number	Lot number	Quantity returned	Name responsible

☐ **Do not have any products to be returned**

_____ Date

_____ Name (capitals)

_____ Customer #

_____ Email address

_____ Shop name

_____ Signature

_____ Phone number

(Add here a stamp of your company)

Please complete the entire form,
sign off and return by August 14th latest to:
Email: backoffice@ote.nl

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