AIN MEDICARE®

Reference No. : *AN2501*
Date : *27 Jan 2025*

URGENT - Field Safety Notice

To all users of the Hypromellose 0.3% w/v Eye Drops without Preservative (AIN Ophthal Mellose), MDA Registration No.: GB5836723-114988.

Re: Hypromellose 0.3% w/v Eye Drops without Preservative (AIN Ophthal Mellose) with safety and performance issues.

Dear customer,

This letter is to inform you of a potential safety and adverse incident to patients when using the Hypromellose 0.3% w/v Eye Drops without Preservative (AIN Ophthal Mellose), 0.8 mL, Batch No.: HE4G0113, HE4G0219 and THE4G005.

When does this malfunction occur and what are the potential risks?

This Field Safety Notice is issued to address reported complaints related to Hypromellose 0.3% w/v Eye Drops without Preservative (AIN Ophthal Mellose). Patients have reported experiencing adverse effects, including red eyes, stinging sensations, and allergic reactions after using the product. Some users noted that the eye drops were ineffective in relieving dry eye symptoms, while others experienced pain, discomfort, and blurred vision following each dose. These complaints indicate potential deficiencies or malfunctions in the product, which could lead to risks for users.

Some users may also have experienced undiagnosed allergic reactions requiring attention. Additionally, prolonged symptoms of discomfort, pain, or vision disturbances may have delayed necessary treatments or corrective actions.

What steps can the user take to avoid the potential risk of this issue?

The batch affected has been identified and we recommend healthcare professionals to review patient's previous medical history and allergies conditions. We would like to remind user to carefully read Information for Use (IFU) for the ingredients and other relevant informations.

Please take the following precautions;

1. Do not use if you are sensitive to any ingredients in this product.
2. Discard 12 hours within opening.
3. Stop use if you experience eye pain.
4. Stop use if you experience changes in vision.
5. Stop use if you experience continued redness or irritation of the eye.
6. Stop usage if the condition worsens or persists for more than 72 hours.

MS2636
9 082-09/2013

MS2424
5 082-09/2013

ISO 9001 = ISO 14001

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How will the issue finally be resolved?

Ain Medicare Sdn. Bhd. is currently investigating Hypromellose 0.3% w/v Eye Drops without Preservative (AIN Ophthal Mellose) and until it fully investigated, we would suggest not to use for patient with moderate to severe dry eyes and eye injury. The field modification will be available from 1 April 2025.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device. Please inform us about the new owner of the medical device.

The Medical Device Authority will be informed of this notice.

Sincerely Yours,

AIN MEDICARE SDN. BHD. Company No. 88253-D 198201008530

MOHD YUSOF BIN ABDUL RAHMAN
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(NNAZ, AAZ, MNA, RS)

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