

Patient Safety: Removal of Epimax[®] Original Cream, Epimax[®] Paraffin Free Ointment and Epimax[®] Ointment from the Grampian Area Formulary

Summary

Formulary Group has made the decision to remove the following products from the Grampian Area Formulary:

- Epimax[®] Original Cream
- Epimax[®] Paraffin Free Ointment
- Epimax[®] Ointment

Background

In March 2022 a [Shared Learning Summary](#) was shared following reports of patients in NHS Grampian suffering adverse drug reactions (ADRs) when emollient had been applied to the eye area. This was also shared via [MedWatch](#) Newsletter in May 2022.

Aspire Pharma issued a [Field Safety Notice](#) in January 2023 following a cluster of reports in Scotland concerning eye-related injuries sustained by patients following the use of some products from the Epimax[®] range on the skin around the eye area. The Field Safety Notice advised of an update to product labelling/packaging re-iterating the warning to avoid contact with the eyes. Healthcare professionals were asked to ensure patients are aware to avoid contact of these products with their eyes. The Field Safety Notice was shared via [MedWatch](#) Newsletter in March 2023.

In response to the Field Safety Notice NHS Grampian removed the relevant Epimax[®] products as first-line options on the formulary and in May 2024 decided to remove the above Epimax[®] products from the Grampian Area Formulary following a further report locally of an eye-related injury with the use of some products from the Epimax[®] range. In general, patients affected within NHS Grampian were new to using Epimax[®] and were prescribed Epimax[®] for use on the face, however there is also a risk of inadvertent transfer from hands to the eyes when Epimax[®] is used on other parts of the body.

Since this decision by Formulary Group Aspire Pharma issued a second [Field Safety Notice](#) in June 2024 relating to Epimax[®] Ointment and Epimax[®] Paraffin Free Ointment. This field safety notice advises of further changes to the product label to include:

- restrict the product to use on the body and not to use the product on the face
- wash hands after use
- further emphasise the warnings about avoiding contact with eyes.

The MHRA published a [Drug Safety Update](#) on 23rd July 2024 advising healthcare professionals of the points in the Aspire Pharma Field Safety Notice.

Actions for Prescribers

Prescribers are advised not to commence any new patients on Epimax® Original Cream, Epimax® Paraffin Free Ointment or Epimax® Ointment and should consult Grampian Area Formulary for an appropriate alternative. In Primary Care Script Switch can also help with this.

Patients currently prescribed Epimax® Paraffin Free Ointment or Epimax® Ointment on their face should be switched to an alternative product.

Patients who are already established on and are safely using Epimax® Original Cream may continue to have this prescribed but should be advised to avoid contact with the eyes. Future prescription instructions should be updated to specify to “Avoid contact with the eyes. If product does accidentally come in contact with eyes, rinse well with water and seek medical advice”.

Patients who are already established on and are safely using Epimax® Paraffin Free Ointment or Epimax® Ointment on their body may continue to have this prescribed for their body but should be advised not to use the product on their face and to avoid contact with the eyes. Future prescription instructions should be updated to specify “Do not use on the face/avoid contact with the eyes. If product does accidentally come in contact with eyes, rinse well with water and seek medical advice”.

All patients prescribed emollients should be advised to wash their hands with soap/soap substitute and water and dry thoroughly after applying the products to avoid inadvertent transfer to the eye area.

Actions for Primary Care

Where available GP Practices could set up SMS text messaging for all patients with an active prescription for Epimax® Original Cream, Epimax® Paraffin Free Ointment or Epimax® Ointment with the following reminder message “The Epimax® product you have been prescribed should NOT come into contact with the eyes. Always wash hands using soap/soap substitute and water after applying the product to avoid inadvertent transfer to the eye area. If the product does accidentally come in contact with eyes, rinse well with water and seek medical advice.”

Actions for Community Pharmacies

When dispensing Epimax® Original Cream, Epimax® Paraffin Free Ointment or Epimax® Ointment Community Pharmacies should counsel patients on the safe use of the product highlighting to avoid contact with the eyes and to wash their hands with soap/soap substitute and water and dry thoroughly after applying the products to avoid inadvertent transfer to the eye area.

Consider adding a warning to dispensing labels highlighting to avoid contact with the eyes.

Patient Awareness Messaging Summary

Anyone prescribing or dispensing Epimax® Original Cream, Epimax® Paraffin Free Ointment or Epimax® Ointment to patients should ensure that the patient is aware that:

- When applying the product always read the label and avoid contact with eyes.
- Epimax® Paraffin Free Ointment and Epimax® Ointment must not be used on the face.
- The products remain safe to use on other areas of the body.
- They should wash their hands with soap/soap substitute and water and dry thoroughly after applying the products to avoid inadvertent transfer to the eye area.
- If the product does accidentally come in contact with eyes, rinse well with water and seek medical advice

Any queries relating to this information should be directed to Lindsay Cameron, Medication Safety Advisor, lindsay.cameron2@nhs.scot