Medicines & Healthcare products Regulatory Agency

Drug Safety Update

Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

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Contents

The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.

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NICE has accredited the process used by the MHRA to produce Drug Safety Update guidance. More information on accreditation can be viewed on the NICE website.

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This month we remind healthcare professionals to be alert to reports of ocular surface toxicity and ocular chemical injury when Epimax Ointment and Epimax Paraffin-Free Ointment are used on the face. Healthcare professionals should not prescribe or advise the use of these products on the face and advise patients to wash their hands thoroughly and avoid touching their eyes after product application.

Finally, we provide a summary of recent letters and notifications sent to healthcare professionals about medicines and medical devices.

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Epimax Ointment and Epimax Paraffin-Free Ointment: reports of ocular surface toxicity and ocular chemical injury

Epimax Ointment and Epimax Paraffin-Free Ointment can harm the eyes if used on the face. Do not prescribe these ointments for use on the face. Tell patients to wash their hands and avoid touching their eyes after using these products.

Advice for healthcare professionals:

- do not prescribe or advise use of Epimax Ointment or Epimax Paraffin-Free Ointment on the face
- be aware that if Epimax Ointment or Epimax Paraffin-Free Ointment comes into contact with the eyes, patients may present with pain, swelling, redness or watering of eyes, sensitivity to light, blurred vision, burning or grittiness
- symptoms should resolve with discontinuation of the product around the eyes and can be treated with topical lubricants, topical antibiotics or topical steroids as required
- follow the advice in the manufacturer's Field Safety Notice
- healthcare professionals should report suspected adverse reactions associated with Epimax Ointment or Epimax Paraffin-Free Ointment via local and national reporting systems as described under the 'report suspected reactions' section further below in the article

Advice for healthcare professionals to provide to patients:

- do not use Epimax Ointment or Epimax Paraffin-Free Ointment on your face as it has been reported to cause serious symptoms if it comes into contact with your eyes. It is only for use on the body
- wash your hands thoroughly after applying Epimax Ointment or Epimax Paraffin-Free Ointment and avoid touching your eyes after using these products
- if the product accidentally gets into your eyes, rinse well with water and seek medical advice

Background

Epimax Ointment and Epimax Paraffin-Free Ointment are emollients, which are used to treat eczema, psoriasis and dry skin conditions. These specific products are regulated as medical devices, although some emollients are regulated as medicines.

The manufacturer, Aspire Pharma, previously issued a warning to users via a Field Safety Notice on 20 January 2023, following a cluster of reports concerning ocular surface toxicity and ocular chemical injury in Scotland. These cases have subsequently been published.[1]

The case series reported novel ocular surface toxicity in 37 patients, related closely (often less than 1 week) to Epimax initiation. Most patients reported subjectively reduced visual acuity, frequently associated with photophobia. There was significant symptom resolution by first follow up appointment (average 7.3 days).[1]

In 2023 Aspire Pharma updated the product labelling to include advice on what to do if the product comes into contact with the eyes by accident, and to explain that it can be used as a body wash and not as a soap substitute that might be used on the face and around the eyes.

Following further similar reports across the UK, Aspire Pharma issued another Field Safety Notice on 13 June 2024 to inform patients and healthcare professionals that product information would be updated to restrict use of the product to the body and to not use the product on the face, to wash hands after use and to further emphasise the warnings about avoiding contact with the eyes.

See page 3 of the Field Safety Notice for the most up to date Epimax Ointment product labelling, and page 4 of the Field Safety Notice for the most up to date Epimax Paraffin-Free Ointment product labelling.

Report suspected reactions

Patients and caregivers should report suspected adverse reactions associated with all emollients, including Epimax Ointment or Epimax Paraffin-Free Ointment, to the Yellow Card scheme.

As these specific ointments are classed as medical devices, there are specific reporting arrangements for healthcare professionals to follow in each region of the UK. An emollient which is regulated as a medical device will have a CE or UKCA mark. If it is regulated as a medicine, it will have a product licence (PL) number. See guidance for reporting on adverse reactions on the Yellow Card website.

Healthcare professionals should report incidents involving medical devices:

- in England and Wales to the Yellow Card scheme or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system.

When reporting, please provide as much information as possible, including information about batch numbers, medical history, onset timing, treatment dates, and product brand name.

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References

1. Mulholland C and others. ‘Epimax-Related Ocular Surface Toxicity (EROST): the Glasgow experience’ Eye 2023: volume 37, pages 3869 to 3870.

Letters and medicine recalls sent to healthcare professionals in June 2024

A summary of recent letters and notifications sent to healthcare professionals about medicines and medical devices.

Letters

In June 2024, the following letters were sent or provided to relevant healthcare professionals:

- VABYSMO®▼(faricimab): tear in primary packaging of Transfer Filter Needle (TFN) co-packaged with vial localised in Northern Ireland

- VERORAB, powder and solvent for suspension for injection - PLGB 46602/0029 Interim Supply of UK Stock in Standard Export Packaging (Standard Export Packs) to Mitigate Supply Disruption

Medicine Recalls and Notifications

In June 2024, recalls and notifications for medicines were issued on:

Class 4 Medicines Defect Information: Manx Healthcare Ltd., Betamethasone Valerate 0.1% Ointment, EL(24)A/18. Issued 3 June 2024. Manx Healthcare Ltd. has informed MHRA that they have identified a problem with the product packaging of the batch indicated in the table. The tamper-evident seal on the outer carton may be missing or deformed on some packs. This is due to an intermittent equipment fault during secondary packaging.

Class 3 Medicines Recall: Neuraxpharm UK Ltd, Atomoxetine 10mg, 18mg, 25mg, 40mg Capsules, EL(24)A/19. Issued 5 June 2024. Neuraxpharm UK Ltd is recalling the above batches after retesting showed out of specification results. The tabled batches are being recalled as a precautionary measure after testing showed variability of the capsule contents beyond permitted levels.

Class 2 Medicines Recall: Desitin Pharma UK Ltd, Lamotrigine Desitin 10mg/ml Oral Suspension, EL(24)A/20. Issued 6 June 2024. Desitin Pharma UK Ltd is recalling all batches of Lamotrigine Desitin 10mg/ml Oral Suspension as a precautionary measure due to an out of specification observation in the appearance of samples during routine stability testing. Please note this is a Class 2 Patient, Pharmacy and Wholesaler level recall.

Class 4 Medicines Defect Information: Dawa Limited, Paracetamol 500mg, 1000mg Film-Coated Tablets, EL (24)A/21. Issued 10 June 2024. Dawa Limited has informed the MHRA that specified batches listed in this notification have been packed with an outdated Patient Information Leaflet (PIL).

Class 4 Medicines Defect Information: Viatris UK Healthcare Ltd, Oxcarbazepine Mylan 150mg, 300mg, 600mg Film-Coated Tablets, EL (24)A/22. Issued 17 June 2024. Viatris UK Healthcare Limited has informed the MHRA that the Patient Information Leaflet (PIL) packaged in the specified batches of Oxcarbazepine 150 mg, 300 mg & 600 mg Film-Coated Tablets do not contain the most up to date safety information.

Class 3 Medicines Recall: Teva UK Limited, GoResp Digihaler, EL (24)A/23. Issued 18 June 2024. Teva UK Limited has informed the MHRA that it plans to withdraw from further sale all batches of GoResp Digihaler (budesonide and formoterol fumarate dihydrate) and the linked Digihaler App for commercial reasons.

Class 4 Medicines Defect Information: PHARMATHEN S.A., Grepid 75 mg film coated tablets (Kent Pharma Livery), EL(24)A/24. Issued 24 June. PHARMATHEN S.A. has informed the MHRA that the outer carton (box) of some batches of Grepid 75mg film coated tablets is missing the medicines legal classification for a Prescription Only Medicine 'POM.' This notification contains additional batches impacted by this issue.

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