Epimax-Related Ocular Surface Toxicity (EROST): The Glasgow Experience

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Introduction



- Atopic eczema is the most common chronic inflammatory skin condition (2-10% UK adult lifetime prevalence).[1] Primary management involves frequent, liberal use of emollients and moisturisers to affected areas.
- In September 2021, our local formulary committee changed the first-line emollient management of atopic eczema to Epimax cream/ointment (Aspire Pharma).
- We identified patients presenting to acute ophthalmic services with unexplained ocular surface toxicity in the context of recent Epimax ointment/cream use.

Methods

- A retrospective case-note review of emergency eye clinic attendances for NHS Greater Glasgow and Clyde.
- Patients within this study initially presented between 24th January 2022 and 28th October 2022, with evidence of recent initiation of Epimax treatment.
- Presentation at our local ophthalmology clinical governance meeting led to additional patients being reported following dissemination of reporting guidance via the corneal/primary care consultants who were managing these patients, including guidance on submitting yellow cards via the MHRA website.

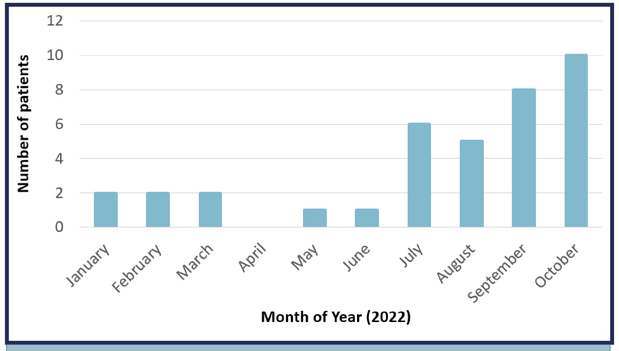
Results

- We identified 37 patients with novel ocular surface toxicity (see graph), related in time-period to initiation of Epimax use (12 male and 25 female, median age of 42 years (range 8-95). Most patients reported using Epimax ointment (23/37, 62.2%)
- The majority of patients described reduced vision, commonly with associated photophobia (33/37, 89.2%), and also had bilateral ocular involvement (25/37, 67.6%).
- Corneal staining was documented in 36 patients (97.3%) and corneal oedema in 10 patients (27.0%). (See clinical photographs below).
- There were 4 patients (10.8%) with complete/near complete corneal epithelial defects. No patients had evidence of limbal ischaemia.



Composite of anterior segment photographs of Epimax related ocular surface toxicity, showing corneal staining and haze (A, B), total corneal defect (C) and corneal oedema and Descemet's membrane folds (D).

- One adult patient (2.7%) required overnight admission to the local Eye ward.
- Patients had an average ocular pH of 7.43.
- Most patients received varying combinations of topical lubricants (32/37; 86.5%), topical antibiotics (27/37; 73.0%) and topical steroids (24/37; 64.9%).
- The mean improvement in visual acuity across all affected eyes with available follow up data (including bilateral cases) was 15.8 EDTRS letters measured at the first follow up appointment.
- The average time to review following initiation of treatment was 7.26 days (range 2-34)
- No geographic clustering identified.



Graph showing timeline of patients using Epimax products and presenting to acute eye services with ocular surface toxicity each month in 2022.

Discussion

- We report the first large case series of patients presenting to ophthalmology services with novel ocular surface toxicity in the context of recent Epimax product use, most commonly Epimax ointment.
- These ocular chemical injuries resolved promptly with cessation of use and topical lubricants and steroids.

Recommendations

- Following yellow card reports via the MHRA website, a Field Safety Notice (reference 5032139) was issued on 20/01/2023 linking cetostearyl alcohol (a known skin sensitiser) to eye related toxicity.[2] Affected medical devices were 'Epimax ointment', 'Epimax Paraffin ointment' and 'Epimax original cream'. Patients should avoid periocular application of Epimax, and healthcare professionals made aware of this potential association.

References

- Pawankar R, Canonica GW, ST Holgate ST, Lockey RF, Blaiss M. The WAO White Book on Allergy (Update. 2013)
- Medicines & Healthcare products Regulatory Agency. MHRA Field Safety Notice 20/1/23. https://mhra-gov.filecamp.com/s/d/m5s053taVYNDbqou. Accessed online on 06/05/2023.