Chief Medical Officer Directorate Pharmacy and Medicines Division



9 June 2023

Medicine Supply Alert Notice

Bromfenac (Yellox[®]) 900 micrograms/ml eye drops

Priority: Level 2^{*} Valid until: w/c 3 July 2023

Issue

- 1. Bromfenac (Yellox[®]) 900 micrograms/ml eye drops are out of stock until w/c 3 July 2023.
- 2. Ketorolac trometamol 0.5% w/v eye drops remain available and will be able to support an increase in demand.
- 3. Unlicensed supplies of bromfenac 900 micrograms/ml eye drops may be sourced, lead times vary.
- 4. Other non-steroidal anti-inflammatory eye drops also remain available but are unable to provide an uplift in demand (See Additional information).

Advice and Actions

- 5. Where supply of licensed bromfenac 900 micrograms/ml eye drops is not available, clinicians should:
 - consider prescribing ketorolac 0.5% w/v eye drops which is able to support the market during this time, ensuring that the patient is not intolerant to any of the excipients and is counselled on the appropriate dose to administer; or
 - consider prescribing unlicensed products only where licensed alternatives are not appropriate.

Additional Information

Clinical Information

- 6. Bromfenac eye drops are licensed for use in adults for the treatment of postoperative inflammation following cataract surgery. One drop is instilled in the affected eye(s) twice daily, beginning the next day after cataract surgery and continuing through the first 2 weeks of the postoperative period. Treatment should not exceed 2 weeks as safety data beyond this is not available.
- 7. Alternative non-steroidal anti-inflammatory eye drops includes ketorolac trometamol, diclofenac, flurbiprofen and nepafenac eye drops, but only ketorolac trometamol can support an uplift in demand at present.

8. Ketorolac trometamol 0.5% w/v eye drops are licensed for the prophylaxis and reduction of inflammation and associated symptoms following ocular surgery in adults. One drop is instilled into the eye three times daily starting 24 hours pre-operatively and continuing for up to three weeks post-operatively.

Guidance on ordering and prescribing unlicensed imports

- 9. The following specialist importers have confirmed they can source unlicensed bromfenac 900 micrograms/ml eye drops (please note there may be other companies that can also source supplies):
 - Mawdsleys
 - Target Healthcare
- 10. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board or local governance procedures. Please see the links below for further information:
 - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA)
 - <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
 - <u>Prescribing unlicensed medicines</u>, General Medical Council (GMC).
- 11. Please refer to the links below for further information:
 - <u>SmPC Yellox® 0.9mg/ml eye drops solution</u>
 - SmPC Ketorolac trometamol 0.5% w/v eye drops, solution

Specialist Pharmacy Service (SPS) website

- 12. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues.
- 13. To access the online Medicines Supply Tool you need to register with the <u>SPS website</u>. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 14. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool in order to stay up to date concerning medicines supply disruptions.
- 15. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

 Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <u>PharmacyTeam@gov.scot</u> (primary care) or <u>NSS.NHSSMedicineShortages@nhs.scot</u> (secondary care).