Chief Medical Officer Directorate Pharmacy and Medicines Division



11 July 2025

Medicine Supply Alert Notice

Diclofenac (Voltarol[®] Ophtha) 0.1% eye drops 0.3ml unit dose preservative free

Priority: Level 2^{*} Valid until: early October 2025

Issue

- 1. Diclofenac (Voltarol[®] Ophtha) 0.1% eye drops 0.3ml unit dose **preservative free** are out of stock until early October 2025.
- 2. Ketorolac 0.5% eye drops, bromfenac 0.9mg/ml eye drops, and nepafenac 1mg/ml and 3mg/ml eye drops remain available and can support increased demand (all contain preservative benzalkonium chloride).
- Diclofenac (Voltarol[®] Ophtha Multidose) 0.1% eye drops, which also contain benzalkonium chloride, are currently out of stock until late July 2025, but can support increased demand once back in stock. Please refer to the <u>Medicines Supply Tool</u> located on the Specialist Pharmacy Service (SPS) website (registration required) for further information and updates to anticipated resupply date.
- 4. Preservative free corticosteroid eye drops remain available.

Advice and Actions

- 5. Prescribers should not initiate new patients on Voltarol[®] Ophtha 0.1% eye drops 0.3ml unit dose preservative free until the shortage has resolved and should liaise with pharmacy teams to reserve existing stock for patients considered unsuitable for preservative containing formulations.
- 6. For new patient initiations and existing patients who have insufficient supplies to last until the re-supply date, prescribers should review on a case-by-case basis to determine suitability of switching to a **preservative containing** non-steroidal anti-inflammatory eye drop, and if suitable:
 - consider prescribing ketorolac 0.5% eye drops or bromfenac 0.9mg/ml eye drops or nepafenac (1mg/ml or 3mg/ml) eye drops; diclofenac (Voltarol[®] Ophtha Multidose) 0.1% eye drops will be another option once back in stock in late July 2025.
 - when prescribing these products, refer to local formulary/guidance and treatment history, noting their use may lead to off label prescribing in some instances (see Additional information and refer to SmPC for dosing, contraindications, cautions and excipients); and
 - consider if measures to reduce risk of irritation in those prescribed a preservative containing preparation is needed, including switching other eyedrops being used to preservative free formulations, and the use of lubricating eye drops if eyes become itchy/dry.

7. If the above options are not suitable, specialist advice should be sought on management options, including appropriateness/safety of using **preservative free** corticosteroid eye drops.

Additional Information

Clinical information

 NSAID eye drops have a common mechanism of action but vary in their licensed indications and marketed uses. Of the licensed NSAID eyedrops, only Voltarol[®] Ophtha 0.1% eye drops 0.3ml unit doses are preservative free.

Product	Voltarol [®] Ophtha 0.1% eye drops 0.3ml unit dose preservative free	Voltarol [®] Ophtha Multidose	Ketorolac trometamol 0.5% w/v eye drops, solution	Yellox [®] 0.9 mg/ml eye drops solution	Nevanac [®] 1mg/ml and 3mg/ml eye drops suspension*
Active ingredient	Diclofenac		Ketorolac	Bromfenac	Nepafenac
Licensed indication(s)	 Inhibition of peropera cataract surgery Treatment of post-ope inflammation in catara Control of ocular pain associated with corne defects after excimer accidental non-penetit Control of inflammatic Laser Trabeculoplasty Relief ocular signs/sy Seasonal Allergic Cor Treatment of inflamm after strabismus surge Treatment of ocular p after radial keratotom 	erative act surgery /discomfort eal epithelial PRK surgery or rating trauma on after Argon y mptoms of njunctivitis ation/ discomfort ery ain/discomfort	Prophylaxis and reduction of inflammation and associated symptoms following ocular surgery	Treatment of postoperative ocular inflammation following cataract extraction	 Prevention and treatment of postoperative pain and inflammation associated with cataract surgery Reduction in risk of postoperative macular oedema associated with cataract surgery in diabetic patients

*Once-daily dosing with 3 mg/ml eye drops provides the same total daily dose of nepafenac as three-times-daily dosing with 1 mg/ml eye

9. Benzalkonium chloride is the most widely used preservative in eyedrops. It may have an adverse effect on the ocular surface in some patients, especially with use of multiple eye drops containing preservatives, and with chronic exposure, leading to pain and discomfort

Links to further information

- <u>SmPC Voltarol Ophtha Unit Doses</u>
- <u>SmPC Voltarol Ophtha Multidose</u>
- SmPC Ketorolac trometamol 0.5% eye drops
- <u>SmPC Yellox 0.9 mg/ml eye drops solution</u>
- <u>SmPC Nepafenac</u>
- BNF Eye, allergy and inflammation
- NICE CKS Conjunctivitis allergic

Specialist Pharmacy Service (SPS) website

- 10. 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. 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.
- 11. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. 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

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