NHS Circular:
MSAN (2019) 18

Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

Medicine Supply Alert Notice

Medicine in short supply: Minims phenylephrine 2.5% and 10% w/v eye drops

Priority: Level 3

Valid until: January 2020

Issue

1. Bausch and Lomb are experiencing supply issues across their phenylephrine Minims range.
2. Minims phenylephrine 2.5% eye drops will be out of stock from the end of November 2019 until early January 2020.
3. Minims phenylephrine 10% eye drops are now out of stock until early January 2020.
4. Limited unlicensed imports can be sourced.
5. The Royal College of Opthalmologists (RCOphth) has provided clinical guidance to support local prioritisation of remaining supplies and advice on alternative options where appropriate.

Advice and Actions

6. All healthcare professionals who prescribe, dispense or administer phenylephrine eye drops should:

- Centralise remaining supplies held at clinic, ward and theatre locations.
- Ensure they are designated for high priority areas as identified in the RCOphth guidance attached, after discussions with local opthalmologists.
- Discuss alternatives for other, medium and low priority, indications with local opthalmologists;
- Restrict ordering to two weeks stock (wholesalers will monitor and manage remaining supplies as they see sensible based on historic demand) and ensure this is designated to high priority areas in accordance with RCOphth guidance; and
- Immediately place orders for unlicensed imports where available.

Additional Information

7. The RCOphth clinical guidance is contained in Annex B.

Action

8. **Healthcare professionals are asked to note the content and actions outlined in this circular and Annex.**

Enquiries

9. Any enquiries should be directed to – PharmacyTeam@gov.scot or NSS.NHSSMedicineShortages@nhs.net – delete as appropriate

ANNEX A

CLASSIFICATION OF MEDICINE SHORTAGES

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration **(up to one month**) where immediately available measures are expected to be sufficient and there is minimal additional management requirement.	Business as usual. Response likely to involve using the same medicine. • Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where alternatives in the same therapeutic class are available but which may require some management such as switching to those alternatives, which may include unlicensed medicines.	Business as usual. Response not likely to require a change in the class of medicine. • Alternative strength/formulation available but clinical advice is required to help manage the switch. • Alternative medicine in the same therapeutic class. • Unlicensed alternatives may be used. • Issuing a Medicine Supply Alert Notice.
Level three (high impact)	Supply problems where there are limited or no alternatives in the same therapeutic class and which require significant management, potentially including changes in clinical practice or operational direction or that have patient safety implications. Level three shortages also include level two shortages for medicines used in life saving conditions such as anaphylaxis or involving patient groups considered as vulnerable, such as neonates, paediatrics or people with learning disabilities.	Serious shortage situation. Response likely to require a change in the class of medicine. • Alternative therapeutic class of medicine available. • The use of a 'serious shortage protocol'. • Additional clinical advice. • Exceptional MHRA regulatory measures. • Issuing a Medicine Supply Alert Notice.
Level four (critical impact)	Supply problems where there is no viable therapeutic alternative and where responses may also require support from outside the health system and / or which trigger the use of national resilience structures.	Very serious shortage situation. Wider burden on NHS and public sector. • Non-medicine support provided to patients. • National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required. • Issuing a Medicine Supply Alert Notice.

Clinical Guidance

The RCOphth has provided the following clinical advice which outlines high/medium/low priority indications for the use of phenylephrine eye drops. This table should be used to support local prioritisation to help preserve stock during this time.

Please note that local ophthalmology teams who use phenylephrine eye drops will need to be consulted for guidance on specific alternatives for the medium and low priority indications where appropriate.

Clinical indication	Comments/Examples (decision based on clinical judgement)
High priority	
Retinopathy of prematurity screening and treatment	• Neonates at risk of retinopathy of prematurity are at high risk of severe vision loss and need assessment and treatment urgently within a very short time frame. • They need very well dilated pupils and, due to risk of systemic adverse effects, are limited in terms of which pupil dilating drops should be used. • Phenylephrine 2.5% is required in combination with other pupil dilating drops.
Patients in whom adequate dilation cannot be obtained with other agents for whom this represents a serious safety risk for diagnosis or care	• Some patients may be at risk of serious visual loss or serious adverse health effects without the use of phenylephrine, usually in combination with other pupil dilating drops, to obtain adequate pupil dilatation, and the use of other agents does not provide adequate visualisation. E.g. Diagnosing or treating a peripheral retinal tear causing a retinal detachment in a patient poorly dilating with other agents, or suspicion of an intraocular tumour in a patient poorly dilating with other agents, or diagnosis of wet macular degeneration in a patient poorly dilating with other agents.
Urgent surgery and procedures where other preparations cannot adequately dilate the pupil	• Eye surgery and procedures where delay would be permanently and significantly harmful to vision or health and where other agents cannot obtain adequate pupil dilatation to undertake the procedure. E.g. retinal detachment surgery in a patient poorly dilating with other agents or laser treatment for proliferative diabetic retinopathy in a patient poorly dilating with other agents
Cataract surgery with intraoperative floppy iris syndrome (IFIS) or high risk of IFIS	• Patients undergoing cataract surgery who develop IFIS or who are at high risk of IFIS require phenylephrine intracamerally, usually constituted using phenylephrine minims, to complete the surgery safely.

Medium priority	
Non-urgent surgery including cataract patients and vitreo-retinal and similar surgery requiring pupil dilation.	• Non-urgent surgery or laser which requires excellent pupil dilation where phenylephrine is required in combination with other agents such as elective cataract surgery, vitrectomy for macular hole, YAG laser capsulotomy. • For surgery, consider whether licensed pre-operative preparations such as Mydriasert or Mydrane may be appropriate or if surgery can be deferred until drug until shortage is fully resolved.
Patients in whom we cannot obtain adequate dilation with other agents for whom this represents a slow to moderate safety risk for diagnosis or care	• Patients poorly dilating with other agents for whom this will affect the ability to accurately diagnose or treat which might delay definitive care and have moderate risk of harm. E.g. diabetic maculopathy in a patient poorly dilating with other agents, Afro-Caribbean patients and uveitis.
Children aged less than 6 months in whom suitable dilation cannot be obtained by cyclopentolate alone	• Very young children require lower concentrations of other pupil dilating agents specifically cyclopentolate to avoid systemic adverse effects. Some will have inadequate dilatation for safe care without phenylephrine. E.g. infants under 6 months with suspected congenital cataracts or structural abnormalities at the back of the eye or possible significantly reduced vision in a patient poorly dilating with other agents.
Low priority	
All other indications	• Patients for whom phenylephrine might result in better or more rapid pupil dilatation but whose diagnosis and care can be safely achieved with other agents e.g. a glaucoma or retinal patient who will wait longer in clinic until adequate pupil dilatation is achieved to assess the back of the eye. • Patients who do not need phenylephrine in whom other agents can adequately dilate the pupil e.g. a patient with a retinal vein occlusion or macular disease whose pupils dilate with other agents so that assessment might be limited but adequate for safe care.