Department of Health & Social Care

NHS

Supply Disruption Alert

SDA/2019/008 Issued: 14 November 2019 Valid until: 10 January 2020

Minims phenylephrine 2.5% and 10% w/v eye drops – Supply Disruption Alert

Summary

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

Action

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 below, after discussion with local ophthalmologists;
- discuss alternatives for other, medium and low priority, indications with local ophthalmologists;
- 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.

Deadlines for actions

Actions initiated: 15 November 2019
Actions completed: 10 January 2020

Product details

Minims Phenylephrine Hydrochloride 2.5%w/v Eye Drops, Solution
Minims Phenylephrine Hydrochloride 10%w/v Eye Drops, Solution

Problem / background

Bausch and Lomb are the sole UK supplier of Minims Phenylephrine Hydrochloride eye drops. This supply disruption has been caused by an active pharmaceutical ingredient shortage. There are no alternative UK suppliers of preservative-free or preservative containing phenylephrine eye drops.

Specialist importer companies have confirmed that they can source unlicensed supplies of preservative free phenylephrine eye drops in both strengths, but the quantities are limited. There are enough unlicensed supplies of phenylephrine 10% w/v eye drops available to meet normal UK demand until end of January 2020. However, there is insufficient unlicensed supplies of phenylephrine 2.5% w/v eye drops available to meet normal UK demand.

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.

Distribution

If you are responsible for cascading this alert in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units

- All departments
- All staff
- All wards
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Chief pharmacists
- Clinical governance leads
- Clinical pathology directors
- Clinical Procurement Specialists [NEW]
- Day surgery units
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Dietetics departments
- General surgeons
- General surgery
- General surgical units, directors of
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Minor injury units
- Maternity units
- Medical directors
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Nursing executive directors
- Ophthalmic nurses
- Ophthalmologists
- Ophthalmology departments
- Ophthalmology, directors of
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments

- Paramedics
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Walk-in centres

NHS England Regional Teams

For onward distribution to all relevant staff including:

- Community optometrists
- Community pharmacists
- Dispensing opticians
- Optometrists
- General practice

Independent distribution

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Enquiries

England
Send enquiries about this notice to the DH Supply Resilience Team, quoting reference number **SDA/2019/008**

Email: supplyresiliencemd@dhsc.gov.uk