



The ROYAL COLLEGE of
OPHTHALMOLOGISTS



Ophthalmic Special Order Products

General Principles

- The Ophthalmic Special Order Products list relates to topical and oral ophthalmic agents. For injectable agents refer to Medusa injectable guide.
- The list is colour coded as follows: **green** for specials suitable for initiation by primary care; **amber** for specials initiated by secondary care and can be continued by primary care; **red** for specials prescribed by secondary care only.
- When clinically appropriate and available, licensed products should always be prescribed and dispensed in preference to unlicensed products.
- Certain products e.g. **sodium chloride 5% w/v eye drops and sodium chloride 5% w/w eye ointment** are now available as prescribable medical devices throughout the UK, **specials should not be used.**
- Where a licensed product is not available, specials products listed on the Drug Tariff for England and Wales part VIII B (Scotland part 7S) or devices listed on the Drugs Tariff for England and Wales part IX A (Scotland part 3, N Ireland part III) are preferred
- Where a preservative-free (PF) preparation is clinically necessary, licensed Single Dose Units (SDUs) or licensed multi-dose devices e.g. Tear-Lac® should be prescribed if available.
- Excipient intolerances should be included on the prescription. Some licensed and unlicensed products, including those labelled preservative-free, contain potentially sensitising excipients (chelating agents such as EDTA)
- All ophthalmic preparations, whether preserved or preservative-free, should only be used for a limited period once opened. Justified and validated in-use shelf lives should be provided by the manufacturer.
- Medicinal Single Dose Units (SDUs) should be used once only in accordance with the licence.
- **For items not on the list, please confirm with secondary care to ensure that a transcription error has not occurred**
- All ophthalmic specials **should be initiated in specialist ophthalmic secondary care only and only prescribed in primary care according to secondary care instructions with secondary care supervision (where appropriate), unless otherwise indicated below.**

<u>Medicinal name and form</u>	<u>Comments and suggested alternatives</u>	<u>Drug Tariff (if applicable)</u>
Anti-infectives		
G. Amikacin 2.5% (25mg/mL) PF 5mL		
G. Amphotericin 0.15% (1.5mg/mL) PF 5mL		
G. Ceftazidime 5% (50mg/mL) PF 5mL		
G. Cefuroxime 5% (50mg/mL) PF 10mL		
G. Chlorhexidine 0.02% (0.2mg/mL) PF 10mL	For infections caused by acanthamoeba.	
G. Chlorhexidine 0.05% (0.5mg/mL) PF 10mL	Prior to intravitreal injection or implant when povidone-iodine cannot be used.	
G. Chlorhexidine 0.2% (2mg/mL) PF 10mL	For fungal infections and infections caused by acanthamoeba. Not first line therapy. The 0.2% can be irritant. For this reason the 0.05% strength is more suitable as antiseptics of conjunctiva pre-injection or implant.	
G. Gentamicin 1.5% (15mg/mL) preserved and PF 10mL	G gentamicin 0.3% is licensed.	
G Natamycin 5% (50mg/mL) preserved 15mL	Import. Unlicensed in the UK but FDA approved in US.	
G. Penicillin 0.3% (3mg/mL) PF 5mL		
G. Polihexanide (polyhexamethylene biguanide or PHMB) 0.02% (0.2mg/mL) PF 10mL	Lower strength may be used as initial therapy for acanthamoeba infection.	
G. Polihexanide (polyhexamethylene biguanide or PHMB) 0.06% (0.6mg/mL) PF 10mL	Higher strength for acanthamoeba infection.	
G. Hexamidine isethionate (Desomedine) 0.1% (1mg/mL) PF 10mL	Import. Alternative treatment in acanthamoeba keratitis.	

<u>Medicinal name and form</u>	<u>Comments and suggested alternatives</u>	<u>Drug Tariff (if applicable)</u>
G.Trifluorothymidine (Trifluridine or F3T) 1% (10mg/mL) preserved 10mL	First line would be licensed ganciclovir 0.15% eye gel (1.5mg/ml). Trifluorothymidine is the second line / alternative option.	
G. Vancomycin 1.4% (14mg/mL) preserved and PF 5mL	For life time prophylaxis for keratoprotheses only. Can switch between formulations (preserved and PF) if no contraindications during product shortage.	
G. Vancomycin 5% (50mg/mL) PF 5mL	For treating gram positive bacterial infections.	
G. Voriconazole 1% (10mg/mL) preserved and PF 5mL	Note that on opening the in-use-expiry of the preserved product will be different (longer) than that of the PF formulation.	
G. Teicoplanin 1% (10mg/mL) PF 4mL	MRSA Keratitis if vancomycin resistance / not able to obtain G vancomycin 5%.	
Oc. Erythromycin 0.5% (5mg/1g) 3.5g tube	Import. Paediatric bacterial infections such as bacterial conjunctivitis, ophthalmia neonatorum. Adult and paediatric blepharitis.	

Acetylcysteine and lubricants		
G.Acetylcysteine 5% (50mg/mL) PF 10mL	For dry eye with mucous tear film in patients intolerant of benzalkonium chloride (Ilube® is a preserved eye drop). Need to confirm patient requires PF form. Currently available product has a very short in-use expiry.	
G.Acetylcysteine 10% (100mg/mL) PF 10mL	For severe dry eye with mucous tear film. Currently available product has a very short in-use expiry.	
Oc Soothe Night 3.5 g tube (contains mineral oil 20% (200mg/mL) and petrolatum 80% (800mg/mL))	Previously known as Duolube®; same manufacturer but changed names. Lanolin free and preservative free.	

Glaucoma		
Acetazolamide 250mg/5mL oral liquid	Standard licensed tablets will disperse in a small volume of water (10-15ml) within 5 minutes. Add juice or squash to disguise taste.	
G.Glycerol 15% (150mg/mL) preserved 10mL	Diagnostic aid.	
G. Pilocarpine 0.1% (1mg/mL) preserved 10mL	Used for diagnostic purposes. Rarely used for glare management e.g. after laser surgery.	
G. Pilocarpine 4% (40mg/mL) PF 10mL	Used intra-operatively for pupil constriction in ophthalmic procedures e.g. iridotomy laser.	

<u>Medicinal name and form</u>	<u>Comments and suggested alternatives</u>	<u>Drug Tariff (if applicable)</u>
G. Adrenaline 0.1% (1mg/mL) PF 10mL	Used intra-operatively in ophthalmic procedures.	
G. Adrenaline 0.01% (0.1mg/mL) PF 10mL	Used intra-operatively in ophthalmic procedures. Lower strength preferred in patients with coronary artery or cardiovascular disease.	

Anti-inflammatories - Corticosteroids		
G.Prednisolone 0.1% (1mg/mL) preserved and PF 10mL	<p>New patients generally should not be initiated. Offer licensed Softacort® (hydrocortisone 3.35mg in 1ml) preservative free in single-dose containers as first line.</p> <p>Prednisolone 0.1% is a lower strength of the licensed product (0.5%) for patients who need a weak steroid to keep their condition under control. Hydrocortisone is a weak steroid and may be a suitable licensed product.</p>	

Anti-inflammatories – Ciclosporin		
Oc.Ciclosporin 0.2% w/w (2mg/g) 3.5g tube*	<p>Usually use licensed ciclosporin unpreserved eye drops 0.1% (Ikervis® or Verkazia in children).</p> <p>Ointment form may be required for severe dry eye, serious ocular surface or corneal inflammation e.g. graft rejection, severe vernal conjunctivitis, and some immune mediated disorders, where intolerant of licensed drops. Preservative-free but contains lanolin. Commercially available as veterinary product Optimune®; source from veterinary wholesaler*.</p>	Avoid import listed in the drug tariff (0.05% PF which costs £6.58 per unit dose).

*Manufacturers and / or wholesalers must have the appropriate licence/authorisation from the MHRA to supply veterinary products.

Miscellaneous		
G.Cysteamine/ Mercaptamine eye drops 0.55% (5.5mg/mL) PF 10mL	For cystinosis. Single source amongst NHS manufacturing units. Licensed product available: Cystadrops 3.8mg/mL. It must be stated that the product needs to be preservative free AND all orders must state the special clinical need requiring this 'special' instead of Cystadrops.	£53.96 in the English drug tariff (April 19). Not in Scottish drug tariff and Northern Ireland

<u>Medicinal name and form</u>	<u>Comments and suggested alternatives</u>	<u>Drug Tariff (if applicable)</u>
Miscellaneous		
G. Disodium edetate 0.37% (3.7mg/mL) PF 10mL	Used for removal of corneal calcium deposits intra-operatively and prophylactically. Also used as a chelating agent.	
G. Ethanol 18% (180mg/mL) preserved 10mL	For one off removal of corneal epithelium as part of a surgical procedure only. Not suitable for primary care.	
G. 5-Fluorouracil 1% (10mg/mL) preserved 10mL	Usually for treatment of ophthalmic malignancies. Not suitable for primary care.	
G. Heparin 5000 IU/mL preserved and PF 5mL	Treatment of ligneous conjunctivitis. Preservative free available as an Italian import.	
G. Interferon alfa 2b 1 million units/mL 5mL	Ocular surface tumour treatment.	
G. Mitomycin 0.02% (0.2mg/mL) PF 5mL	For treatment of ophthalmic malignancies. Not suitable for primary care.	
G. Mitomycin 0.04% (0.4mg/mL) PF 5mL	For treatment of ophthalmic malignancies. Not suitable for primary care.	
G. Potassium ascorbate 10% (100mg/mL) preserved and PF 10mL	Used for the treatment of both acid and alkali burns. Consider whether PF is required.	
G. Riboflavin 0.1% (1mg/mL) single-dose as 1.5mL/unit	Used for corneal collagen cross linking procedure. Available as CE marked products. Not suitable for primary care.	
G. Atropine 0.01% (0.1mg/mL) preserved 10mL	Control of myopia progression in childhood.	
G. Sodium citrate 10.11% (101.1mg/mL) PF 10mL	Used for the treatment of both acid and alkali burns.	

G. = eye drops **Oc.** = eye ointment **PF** = preservative free

Unlicensed specials listed in Drug Tariff for England & Wales in part VIII B, for Scotland in part 7S. Eye drops classed as medical devices are listed in Drug Tariff for England & Wales in part IX A, for Scotland in part 3, for Northern Ireland in part III

Special order manufacturers listed in the British National Formulary (see 'Guidance') are preferred suppliers. NHS suppliers' products are listed on NHS Pro-File (www.pro-file.nhs.uk). Local ophthalmic unit in secondary care may advise on sourcing.

Sodium chloride 5%w/v eye drops and sodium chloride 5%w/w eye ointment are now available as prescribable medical devices throughout the UK (see list below), specials should not be used.

Sodium chloride 5% medical devices Product	<u>Manufacturer</u>	<u>Pack size</u>	<u>In use shelf life</u>	<u>NHS cost April 19</u>	<u>Availability in England & Wales (Part IXA)</u>	<u>Availability in Northern Ireland (Part III)</u>	<u>Availability in Scotland (Part 3)</u>
<u>Preserved eye drops</u>							
Hypersal 5%	Ennogen	10ml (traditional bottle)	1 month	£25.25	Yes	Yes	No
Sodium Chloride 5%	Alissa Healthcare	10ml (traditional bottle)	90 days	£25.25	Yes	Yes	No
<u>Preservative-free eye drops</u>							
NaCl 5% single dose units	Essential Pharmaceutical Ltd.	20 x 0.45ml Unit dose	Single use	£19.70	Yes	Yes	No
PF Drops Sodium Chloride 5%	Rayner Pharmaceuticals	10ml (OSD bottle)	60 days	£25.20	Yes	Yes	Yes
ODM5	Kestrel Ophthalmics	10ml (easy squeeze Preservative Free bottle)	90 days	£24.00	Yes	Yes	Yes
<u>SodiEye</u>	TriOn Pharma	10ml	12 months	£15.98	Yes	Yes	Yes
<u>SodiEye</u>	TriOn Pharma	20 x 0.5mls Unit dose	Single use	£17.70	Yes	Yes	Yes
<u>Eye ointment</u>							
Sodium Chloride 5%	Alissa Healthcare	5g tube	28 days	£22.50	Yes	Yes	Yes

Appendix – definition of specials by different organisations

Definitions:

MHRA

The supply of unlicensed medicinal products (“specials”) MHRA Guidance Note 14

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf

1.3 This Guidance Note provides advice on the manufacture, importation, distribution and supply of unlicensed medicinal products for human use (commonly described as “specials”) which have been specially *manufactured or imported* to the order of a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber for the treatment of individual patients.

Royal Pharmaceutical Society

‘Specials are unlicensed medicines that are specifically manufactured or obtained to meet a patient's individual clinical need.’

<https://www.rpharms.com/resources/toolkits/specials>

Professional Guidance for the Procurement and Supply of Specials December 2015 (RPS)

Specials are a category of unlicensed medicines that does not have either a centrally authorised Marketing Authorisation in the European Union, or a UK Marketing Authorisation and are manufactured, imported or distributed to meet the special clinical needs of an individual patient (see also Definitions below).

Definitions

The Human Medicines Regulations 2012 provide exemptions from the requirement to hold a Marketing Authorisation in certain circumstances. A Special is an unlicensed medicine that does not have either a centrally authorised Marketing Authorisation in the European Union or a UK Marketing Authorisation and is manufactured imported or supplied to meet the special clinical needs of an individual patient. Specials can be obtained from:

- A licensed manufacturer manufacturing medicines or importing them from outside the EEA under a Manufacturer (Specials) Licence (see below); or
- A licensed wholesale dealer importing or distributing medicines from elsewhere in the UK/EEA under a Wholesale Dealer’s Licence (see below).

March 2019 Drug Tariff p3 under definitions

The Drug Tariff has a slightly different definition:

<https://www.nhsbsa.nhs.uk/sites/default/files/2019-02/Drug%20Tariff%20March%202019.pdf>

(k) Specials are unlicensed medicinal products manufactured in the UK for human use which have been specially prepared to meet a prescription ordered for individual patients without the need for the manufacturer to hold a marketing authorisation for the medicinal product concerned.

However the Drug Tariff also states “Specials and imported unlicensed medicines”.