



Clinical Guidance

Ophthalmic Special Order Products

August 2016

The Royal College of Ophthalmologists and the United Kingdom Ophthalmic Pharmacy Group (UKOPG) has produced guidance on the safety and value of certain unlicensed ophthalmic preparations prescribed and dispensed in primary care and to assist general practitioners in making decisions about these products.

The guidance includes a list of a small number of products that are not suitable for prescribing without checking with the initiating ophthalmologist and a list of products suitable for prescribing in primary care along with suggestions for commercially available alternatives and products which may be needed for individual patients with specific requirements.

- 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, these should be prescribed in preference to unlicensed medicines
- Where a licensed product is not available, standard Drug Tariff products are preferred e.g. hypromellose 0.3%w/v or 0.5%w/v rather than 0.25%w/v
- 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)
- Multidose preservative-free preparations should only be used for a limited period once opened. Justified and validated in-use shelf lives should be provided by the manufacturer.
- Single dose units 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.**

Table 1 Products not suitable for prescribing in primary care

British National Formulary name and form	Comments and suggested alternatives	Drug tariff price England & Wales/Scotland as at June 2016 where applicable
Anti-infectives		
G.Amphotericin 0.15%w/v PF multidose	Not suitable for primary care suggest specialist use only	
G.Cefuroxime 0.5%w/v and PF multidose (other strengths may be specified)	Not suitable for primary care suggest specialist use only	
G.Ciprofloxacin 0.2%w/v PF multidose	Not suitable for primary care. 24 hr in-use shelf life as cannot be refrigerated. Licensed ciprofloxacin 0.3%w/w ointment (Ciloxan®) or licensed levofloxacin preservative-free (Oftraquix®) are preservative free alternatives.	
G.Gentamicin 1.5%w/v and PF multidose (other strengths may be specified)	Not suitable for primary care suggest specialist use only	
G.Polyhexanide 0.02%w/v multidose	Not suitable for primary care suggest specialist use only	
G.Trifluorothymidine (Trifluridine) 1%w/v multidose and PF multidose	Not suitable for primary care suggest specialist use only	

Table 2 Products suitable for prescribing in primary care and suggested alternatives

British National Formulary name and form	Comments and suggested alternatives	Drug tariff price England & Wales/Scotland as at June 2016 where applicable
Ciclosporin		
Oc.Ciclosporin 2%w/w	Suggest error, check if 0.2%w/w intended	
Oc.Ciclosporin 0.2%w.w*	Suggest licensed ciclosporin unpreserved eye drops 0.1% (Ikervis®). If ointment form required for patients under 18 for severe dry eye, graft rejection, severe vernal conjunctivitis, some immune mediated disorders. Preservative-free but contains lanolin. Commercially available as veterinary product Optimune®. Source from veterinary wholesaler*. Unlicensed special listed in Drug Tariff (not Northern Ireland or Scotland). Fixed price to NHS in England & Wales only	£81.16 per 3.5g
G.Ciclosporin 0.05%w/v PF SDUs	Suggest licensed ciclosporin unpreserved eye drops 0.1% (Ikervis®). If unit dose form required 0.05%w/v PF SDUs available as licensed product in USA, Restasis®. Licensed in USA as a topical immunomodulator indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. May be imported as ophthalmic special order product. Fixed price in England & Wales only.	£5.78 per 0.4ml unit.

* Veterinary wholesalers will supply to community pharmacists. (Pharmacies dealing with veterinary products may not poses a Wholesale Dealer's licence and therefore only supply against prescriptions from veterinary prescribers).

British National Formulary name and form	Comments and alternatives	Drug tariff price England & Wales/Scotland as at June 2016 where applicable
Acetylcysteine and lubricants		
G.Acetylcysteine 0.5%w/v	Suggest error, check if 5%w/v intended (Ilube®)	
G.Acetylcysteine 5%w/v PF multidose	For dry eye with mucous tear film in patients intolerant of benzalkonium chloride. (Ilube® available which is not preservative free). If PF required confirmed, unlicensed special listed in Drug Tariff in Scotland only. Fixed price to NHS in Scotland. Source from competitive specials manufacturer. Single source amongst NHS manufacturing units.	N/A England and Wales Scotland £57.33 per 10ml
G.Acetylcysteine 10%w/v preserved and PF multidose	For sever dry eye with mucous tear film. Source from competitive specials manufacturer. Singes source amongst NHS manufacturing units.	£40.95 for 10mls
G.Hypromellose 0.1%w/v PF multidose	<u>Preserved</u> – No advantage prescribing strengths other than licensed 0.3%w/v, Unlicensed special list in Drug Tariff (not Northern Ireland). Fixed price to NHS England & Wales only.	
G.Hypromellose 0.25%w/v		Hypromellose 0.25% £14.24 per 10ml
G.Hypromellose 0.25%w/v preservative free multidose	<u>Preservative free</u> – Licensed preservative free single dose units classed as medicines e.g. Artelac® 0.32%w/v and medical devices containing hypromellose 0.3%w/v e.g. Evolve® hypromellose 0.3% preservative free, Hypromellose 0.3% (Alissa Healthcare) preservative free, Hydromoor®, Hypromol®, Lumecare® singles hypromellose 0.3% preservative free, PF drops Hypromellose 0.3%, Ouc-lube®, Softdrops® 0.3% eye drops preservative free, PF Drops® hypromellose 0.3% and Tear-lac® Hypromellose 0.3% PF single dose units, (£1.98-£5.75 for 10ml PF bottle and £4.60 to £5.75 30x0.5ml single PF unit doses). Fixed priced to NHS for 0.25% preservative free (not Northern Ireland)	Hypromellose 0.25% PF £14.04 £41.83 per 10ml for Scotland
G.Hypromellose 0.3%w/v PF multidose		

British National Formulary name and form	Comments and alternatives	Drug tariff price England & Wales/Scotland as at June 2016 where applicable
G.Hypromellose 0.32%w/v PF, 0.5%w/v PF, 1%w/v PF multidose		Hypromellose 0.3% PF £1.98 to £5.75 10mls and £4.60 to £5.75 for 30x05.mls SDU
G.Liquid Paraffin Light, G.Liquid Paraffin	Suggest simple eye ointment, Lacrilube®, Xailin® Night or Vita-POS®	
G.Sodium chloride 0.9%w/v PF multidose	Other lubricants may be more suitable but if required, suggest Xailin Wash (0.3%) or Minims® Saline (0.9%)	
Glaucoma		
Acetazolamide oral liquid Suggest rationalise strength to most frequently prescribed – 50mg/ml (250mg in 5ml)	Tablets will disperse in water. Use solution (not suspension) for fine bore naso-gastric tubes where there is a potential problem of blocking. For small doses e.g. 50mg, suspensions may be administered using an oral syringe. Drug Tariff price include the following formulations: standards formulation including standard flavours; sugar free; alcohol free; colour free; flavour free; lactose free and non-standard flavours. Fixed price to NHS in England & Wales only.	Acetazolamide 250mg/5ml oral suspension £131.40 per 100ml plus 7p for each extra ml above 100ml
G.Glycerol 1%v/v and 10%v/v	Not suitable for primary care suggest specialist use only	
G.Pilocarpine 0.1%w/v, 0.25%w/v, 0.5%w/v	0.1%w/v normally used for diagnosis only. These strengths unlikely to be of benefit, query strength	
G.Pilocarpine 0.4%w/v	Suggest error, check 4%w/v intended	

British National Formulary name and form	Comments and alternatives	Drug tariff price England & Wales/Scotland as at June 2016 where applicable
G.Pilocarpine 1-4%w/v PF multidose	Minims® 2%w/v available if appropriate (no potentially sensitising excipients) or ask ophthalmologist to review. 2% and 4% strengths fixed price to NHS in England & Wales only.	2.0%w/v £80.71 per 10ml; 4.0%w/v £90.96 per 10ml
G.Pilocarpine 6%w/v, 8%w/v	Very high strengths – check with prescriber	
Corticosteroids		
G.Dexamethasone 1%w/v	Suggest error, check 0.1% intended	
G.Dexamethasone 0.1%w/v PD multidose~	Offer licensed single dose units of Dexamethasone Sodium Phosphate 0.1%w/v as alternative (Dexa-free®, Dropodex® or Minims®). Exception could be patient who cannot tolerate phosphate or disodium edetate in licensed products.	
G.Prednisolone 0.003%w/v, 0.005%w/v, 0.01%w/v	Unlikely to be of benefit, query strength and see alternative strengths below.	
G.Prednisolone 0.1%w/v preserved and PF	Preferred strength for patient who require low strength topical corticosteroid. Unlicensed special listed at fixed price in Drug tariff (not Northern Ireland). Only PF form is listed in Scotland	£27.10 per 10ml £53.30 per 10ml for Scotland
G.Prednisolone 0.03%w/v, 0.05%w/v, 0.125w/v preserved and PF multidose	Suggest source 0.1%w/v from competitive NHS manufacturer. Fixed price in NHS for 0.03% and 0.05% strengths in England & Wales (not Northern Ireland or Scotland).	0.3%w/v £22.53 per 10ml

British National Formulary name and form	Comments and alternatives	Drug tariff price England & Wales/Scotland as at June 2016 where applicable
G.Prednisolone 0.3%w/v	Suggest licensed 0.5w/v (Predsol®) or if not available, betamethasone 0.1%w/v (Betnesol®, Vista-methasone®), fluoromethalone (FML®), loteprednol (Lotemax®), or Minims® Prednisolone Sodium Phosphate 0.5%w/v. Unlicensed special listed at fixed price in Drug Tariff in England & Wales (not Northern Ireland or Scotland).	0.3%w/v £22.53 per 10ml
G.Prednisolone 1%w/v PF multidose	This product would be the prednisolone sodium phosphate so not equivalent potency to prednisolone acetate 1%w/v (PredForte®), ascertain prescriber is aware. Offer Minims® Prednisolone Sodium Phosphate 0.5%w/v, Dexafree®, Dropodex® or Minims® Dexamethasone sodium Phosphate 0.1%w/v as alternative. If required source from competitive NHS manufacturer. Fixed price to NHS in England & Wales only.	£43.59 per 10ml
Miscellaneous		
G.Cysteamine/Mercaptamine eye drops 0.11%w/v	For cystinosis. 0.55%w/v is more frequently used. Single source amongst NHS manufacturing units.	
G.Cysteamine/Mercaptamine eye drops 0.44%w/v	May be imported as ophthalmic special order product. Available as licensed product in USA, Cystaran®, CYSTARAN is a cysteine-depleting agent indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.	
G.Cysteamine/Mercaptamine eye drops 0.55%w/v	For cystinosis. Single source amongst NHS manufacturing units. Fixed price to NHS in Scotland only.	N/A £48.85 per 10ml in Scotland
G.Sodium chloride 0.5%w/v and 0.45%w/v (England & Wales only)	Likely to be an error check if 5%w/v or 4.5%w/v – if 4.5%, suggest 5%w/v	

British National Formulary name and form	Comments and alternatives	Drug tariff price England & Wales/Scotland as at June 2016 where applicable
Oc.Sodium chloride 5%w/w (England & Wales only)	Use PF medical device – see table below at £22.50 per 5g. For corneal oedema, recurrent corneal erosion syndrome. Unlicensed eye ointment preserved with methyl parahydroxybenzoate and propyl parahydroxybenzoate also contains lanolin is the unlicensed special listed in Drug Tariff (not Northern Ireland or Scotland). Fixed price to NHS for unlicensed special in England & Wales only.	£27.06 per 5g
G.Sodium chloride PF 5%w/v (no longer classified as an unlicensed medicine as there are several prescribable medical devices available)	For corneal oedema, recurrent corneal erosion syndrome. Use prescribable PF multidose (£24.00-£25.25) licensed medical device, prescribable PF single dose units (£19.70 for 20x 0.45ml single dose units), licensed medical device available in England, Wales & Northern Ireland, or benzalkonium chloride-free sodium chloride 5%w/v eye drops (licensed medical device available in England, Wales & Northern Ireland – see below) which may be acceptable.	
G.Sodium citrate 10.11%w/v	Not suitable for primary care suggest specialist use only	
G.Sodium cromoglicate 2%w/v PF multidose	Suggest commercially available products Catacrom [®] , Opticrom [®] Allergy Single Dose 2%w/v Eye Drops. No potentially sensitising excipients.	
Mydriatics		
G.Atropine 1%w/v PF multidose	Minims [®] Atropine Sulphate 1%w/v may be suitable alternative. No potentially sensitising excipients.	
G.Homatropine hydrobromide 2%w/v PF multidose	Suggest alternative commercially available mydratic-cycloplegic e.g. Minims [®] Cyclopentolate Hydrochloride, Minims [®] Tropicamide. No potentially sensitising excipients.	

G. = eye drops Oc. = eye ointment

Unlicensed specials listed in Drug Tariff for England & Wales in Part VIIB, for Scotland in part 7S.

Eye drops classified as medical devices listed in Drug Tariff for England & Wales in part IXA, 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 listed on NHS Pro-File (www.pro-file.nhs.uk). Local ophthalmic unit in secondary care may advise.

Table 3 Sodium Chloride 5% medical devices

Product	Manufacturer	Pack size	In use shelf life	NHS cost June 2016	Availability in England & Wales (Part IXA)	Availability in Northern Ireland	Availability in Scotland (part 3)
<u>Preserved eye drops</u>							
Hypersal 5%	Emnogen	10ml (traditional bottle)	1 month	£25.25	Yes	Yes	Yes
Sodium Chloride 5%	Alissa Healthcare	10 ml (traditional bottle)	90 days	£25.25	Yes	Yes	Yes
<u>Preservative-free eye drops</u>							
NaCl 5% single dose units	Essential	20x0.45ml unit dose	Single use	£19.70	Yes	Yes	No
PF Drops Sodium Chloride 5%	Moorfields Pharmaceuticals	10ml (OSD bottle)	60 days	£25.20	Yes	Yes	Yes
ODM5	Kestrel Ophthalmics	10ml (east squeeze Preservative Free bottle)	90 days	£24.00	Yes	Yes	Yes

Table 4 Sodium chloride 5% unlicensed medicines

Product	Pack size	Availability in England & Wales (Part VIIB)	NHS cost in England & Wales June 2016	Availability in Northern Ireland	Availability in Scotland (Part 7S)
Eye ointment					
Sodium chloride 5% eye ointment STD	5g tube	Yes	£27.06	No	No