MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Prednefrin Forte eye drops 10mL – 3 March 2021

Details of affected product(s)	Prednefrin Forte (prednisolone acetate 1%, phenylephrine 0.12% suspension) 10mL eye drops – ARTG 23235
Reason for communication	Supply disruption – manufacturing reasons
Shortage commencement date	22 February 2021
Estimated resolution date	1 January 2022

Main therapeutic applications

Severe noninfectious eye inflammation such as acute iritis, iridocyclitis, scleritis, episcleritis, uveitis, resistant ocular allergy and post-surgery e.g. post-operative care for cataract and other intraocular surgery.

Alternative agents

- Equivalent alternatives to the Australian registered prednisolone acetate 1% / phenylephrine 0.12% eye drops (Prednefrin Forte) are unavailable and at this time, there is no provisionally registered product available through Section 19A of the Therapeutic Goods Act.
- Existing Prednefrin Forte stock should be reserved for use in patients where alternative agents may be inappropriate e.g. allergy or clinical indication.
- In the absence of Prednefrin Forte:
  - Dexamethasone 0.1% eye drops (Maxidex) are the preferred alternative (as per ACI Ophthalmology Network). Consult with local Ophthalmology teams for situations where other agents may be preferred.
  - For indications where prednisolone acetate 1% / phenylephrine 0.12% eye drops are essential, sites may wish to consider local aseptic compounding options.
  - Medsurge Healthcare may be able to supply prednisolone acetate 1% (Pred Forte) eye drops via the Therapeutic Goods Administration's Special Access Scheme (SAS). The product is registered in New Zealand, with product information and labelling in English. Lead time is 5-7 business days.
  - LINK Healthcare may also be able to provide prednisolone acetate 1% / phenylephrine hydrochloride 0.12% (Prednefrin Forte) eye drops via the SAS. However, this product does NOT have English packaging or labelling. Lead time is 3-4 weeks.
  - Alternative ophthalmic corticosteroids that continue to be available include fluorometholone 0.1% eye drops (FML), fluorometholone acetate 0.1% eye drops (Flarex) and prednisolone sodium phosphate 0.5% eye drops (Minims).

Precautions and safety issues associated with alternative products

- Prior to the introduction of any alternative, Drug and Therapeutics Committees should assess whether there is a local need for staff education regarding practice changes, providing explanatory information when dispensing the medication, relabeling (particularly if using non-English labelled SAS products) and/or any further safety actions.
- Maxidex is in a 5mL bottle whereas Prednefrin Forte is a 10mL bottle, so sites may need to order increased stock.
- Local strategies such as product separation or dispensing alerts may be required to reduce the risk of sound-a-like errors. Maxidex (dexamethasone 0.1%) eye drops may be confused with Otodex or Sofradex ear drops which also contain dexamethasone. The SAS product Pred Forte (prednisolone acetate 1%) eye drops may be confused with Prednefrin Forte (prednisolone acetate 1% / phenylephrine hydrochloride 0.12%) eye drops.
- As per the Australian Medicines Handbook, the relative anti-inflammatory efficacy of corticosteroid eye drops (with an intact cornea), in descending order, is thought to be prednisolone acetate suspension, 1%, dexamethasone suspension, 0.1%, fluorometholone acetate suspension, 0.1%, fluorometholone suspension, 0.1%, prednisolone sodium phosphate solution, 0.5%. While unlikely, topical overdose can result in systemic sympathomimetic effects such as palpitation, headache, hypertension. Ensure that instructions for use are followed as per product information or ophthalmology advice.

Key contacts

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