

PRODUCT INFORMATION

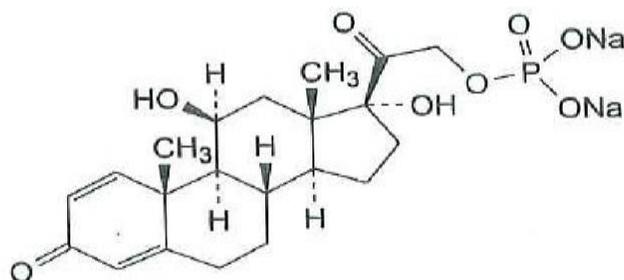
MINIMS[®] PREDNISOLONE EYE DROPS

NAME OF THE MEDICINE

Prednisolone Sodium Phosphate

Synonyms: Prednisolone 21-(disodium orthophosphate)

Structural formula:



Chemical name: 11 β ,17-Dihydroxy-3,20-dioxopregna-1,4-dien-21-yl disodium phosphate

Molecular formula: C₂₁H₂₇Na₂O₈P

Molecular weight: 484.4

CAS number: 125-02-0

DESCRIPTION

Minims Prednisolone Eye Drops are clear, colourless sterile eye drops containing prednisolone sodium phosphate 0.5% w/v as well as disodium edetate, monobasic sodium phosphate, sodium chloride, sodium hydroxide and purified water. No preservatives are contained in the formulation. Each unit contains approximately 0.5mL solution in a container that has a twist and pull cap. Each unit should be discarded after a single use. The solution has a neutral pH.

PHARMACOLOGY

The actions of corticosteroids are mediated by the binding of the corticosteroid molecules to receptor molecules located within sensitive cells. Corticosteroid receptors are present in human trabecular meshwork cells and in rabbit iris ciliary body tissue.

Corticosteroids are thought to act by the induction of phospholipase A₂ inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A₂.

The activation and migration of leucocytes will be affected by prednisolone. A 1% solution of prednisolone acetate has been demonstrated to cause a 51% reduction in polymorphonuclear leucocyte mobilisation to an inflamed rabbit cornea.

Corticosteroids also lyse and destroy lymphocytes. These actions of prednisolone all contribute to its anti-inflammatory effect.

Pharmacokinetics

Aqueous humour levels have been reported in 93 human eyes, dosed with 50 µL of a 0.5% prednisolone sodium phosphate solution, prior to undergoing cataract extraction. Detectable levels were noted at the 90-240 minute interval. Levels were still detectable up to 8 hours after dosing, but not after 10 hours.

INDICATIONS

Minims Prednisolone Eye Drops are indicated for non-infected inflammatory conditions of the eye.

CONTRAINDICATIONS

Minims Prednisolone Eye Drops are contraindicated in the following patient groups / conditions:

- Patients with hypersensitivity to any of the components of the preparation.
- Presence of viral, fungal, tuberculous or other bacterial infection.
- In children, long-term, continuous topical corticosteroid therapy should be avoided due to possible adrenal suppression.
- Glaucoma.

PRECAUTIONS

Minims Prednisolone Eye Drops are for topical ophthalmic use only. The solution should not be injected.

Care should be taken to ensure that the eye is not infected before Minims Prednisolone Eye Drops is used. Corticosteroids may reduce resistance to and aid in the establishment of bacterial, viral, or fungal infections and mask the clinical signs of infection, preventing recognition of ineffectiveness of the antibiotic, or may suppress hypersensitivity reactions to substances in the product. Fungal infection should be suspected in patients with persistent corneal ulceration who have been or are receiving these drugs and corticosteroid therapy should be discontinued if fungal infection occurs. If bacterial infection is present, appropriate anti-bacterial therapy should be used and if the infection does not respond promptly, the corticosteroid should be discontinued and other appropriate therapy initiated.

Steroid medication in the treatment of patients with a history of herpes simplex keratitis requires great caution; frequent slit microscopy is mandatory.

Prolonged application to the eye of preparations containing corticosteroids has caused increased intraocular pressure. If the treating physician determines the clinical need outweighs the risks in patients with glaucoma (see CONTRAINDICATION), intraocular pressure should be closely monitored and any undesirable elevation treated promptly.

Various ocular diseases and long term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of

thin corneal or scleral tissues may lead to perforation.

Systemic absorption of prednisolone may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa.)

Effects on fertility

Studies have not been performed in either animals or humans to evaluate the potential for Prednisolone to impair fertility.

Use in pregnancy (Category B3)

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development and although the relevance of this finding to human beings has not been established, the use of Minims Prednisolone Eye Drops during pregnancy should be avoided.

Use in lactation

Systemically absorbed prednisolone is excreted in breast milk, therefore, use of Minims Prednisolone Eye Drops to breastfeeding mothers is not recommended.

Paediatric use

In children, long-term, continuous topical corticosteroid therapy should be avoided due to possible adrenal suppression (see CONTRAINDICATIONS).

Effects on carcinogenicity and genotoxicity

There are no studies on the carcinogenicity of prednisolone by the topical ocular route. No carcinogenic activity was noted in the mouse at oral doses up to 5 mg/kg/day for 18 months. In male rats, administration of prednisolone in the drinking water at a dose level of 0.4 mg/kg/day for two years caused an increased incidence of hepatocellular tumours. This carcinogenic response does not appear to be related to genotoxic activity.

INTERACTIONS WITH OTHER MEDICINES

Although negligible prednisolone passes into the bloodstream after ocular instillation, drug interactions are nevertheless possible. The interactions observed with prednisolone administered by any route should therefore be taken into account.

Corticosteroids are known to increase the effects of barbiturates, sedative hypnotics and tricyclic antidepressants.

Corticosteroids will, however, decrease the effects of anticholinesterases, antiviral eye preparations and salicylates.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

ADVERSE EFFECTS

Prolonged treatment with corticosteroids in high dosage is occasionally associated with cataract development.

Other ocular effects of corticosteroid therapy reported include: transient ocular discomfort, posterior subcapsular cataracts, ocular hypertension or glaucoma, defects in visual acuity and field of vision, optic nerve damage, decreased resistance to ocular infection, corneal epithelial healing impairment, uveitis, mydriasis and ptosis .

Following long term therapy, systemic effects of steroids are rarely reported but possible following the use of Minims Prednisolone Eye Drops.

DOSAGE AND ADMINISTRATION

Adults and the elderly

One drop applied topically to the eye as required.

Children

At the discretion of the physician.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa.).

Each Minims Prednisolone Eye Drops unit should be discarded after a single use.

OVERDOSAGE

Overdosage with Minims Prednisolone Eye Drops is unlikely to occur.

PRESENTATION AND STORAGE CONDITIONS

Presentation: Minims Prednisolone Eye Drops are supplied as a clear colourless sterile eye drops in a single use polypropylene tube (unit) overwrapped in a polyester/paper blister. The blisters are packed in cartons of 20 units. Each unit contains approximately 0.5 mL solution.

Storage conditions: Store at 2°C to 8°C. (Refrigerate. Do not freeze.). Do not expose to strong light.

Each Minims Prednisolone Eye Drops unit should be discarded after a single use.

NAME AND ADDRESS OF THE SPONSOR

iNova Pharmaceuticals (Australia) Pty Ltd
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Chatswood, NSW 2067

POISON SCHEDULE OF THE MEDICINE

S4 – Prescription Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (the ARTG)

18 June 2009

DATE OF MOST RECENT AMENDMENT

31 March 2017