NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Minims Prednisolone Sodium Phosphate

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing prednisolone sodium phosphate BP 0.5% w/v.

3. PHARMACEUTICAL FORM

Single-use, sterile eye drops.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Non-infected inflammatory conditions of the eye.

4.2 Dose and method of administration

Adults and the elderly:
One or two drops applied topically to the eye as required.

Children:
At the discretion of the physician.

4.3 Contraindications

Use is contraindicated in viral, fungal, tuberculous and other bacterial infections.

Prolonged application to the eye of preparations containing corticosteroids has caused increased intraocular pressure and therefore the drops should not be used in patients with glaucoma.

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

4.4 Special warnings and precautions for use

Care should be taken to ensure that the eye is not infected before Minims Prednisolone is used.

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. It is especially advisable in children.)

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

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

They 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.

4.6 Fertility, pregnancy and lactation

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 during pregnancy should be avoided.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

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

The systemic effects of steroids are possible following the use of Minims Prednisolone, but are, however, unlikely due to the reduced absorption of topical eye drops.

4.9 Overdose

As Minims are single dose units, overdose is unlikely to occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

Prednisolone, in common with other corticosteroids, will inhibit phospholipase A2 and thus decrease prostaglandin formation.

The activation and migration of leucocytes will be affected by prednisolone. A 1% solution of prednisolone has been demonstrated to cause a 5.1% reduction in polymorphonuclear leucocyte mobilisation to an inflamed cornea. Corticosteroids will also lyse and destroy lymphocytes. These actions of prednisolone all contribute to its anti-inflammatory effect.

5.2 Pharmacokinetic properties

The oral availability, distribution and excretion of prednisolone is well documented. A figure of 82 ± 13% has been quoted as the oral availability and 1.4 ± 0.3ml/min/kg as the clearance rate. A half life of 2.1 - 4.0 hours has been calculated.

With regard to ocular pharmacokinetics, prednisolone sodium phosphate is a highly water soluble compound and is almost lipid insoluble. Therefore, theoretically it should not penetrate the intact corneal epithelium. Nevertheless, 30 minutes after instillation of a drop of 1% drug, corneal concentrations of 10µg/g and aqueous levels of 0.5µg/g have been attained. When a 0.5% solution was instilled in rabbit eyes every 15 minutes for an hour, an aqueous concentration of 2.5µg/ml was measured. Considerable variance exists in the intraocular penetration of prednisolone depending on whether the cornea is normal or abraded.

It can be seen that only low levels of prednisolone will be absorbed systemically, particularly where the cornea is intact.

Any prednisolone which is absorbed will be highly protein-bound in common with other corticosteroids.

5.3 Preclinical safety data

The use of prednisolone in ophthalmology is well-established. Little specific toxicology work has been reported, however, the breadth of clinical experience confirms its suitability as a topical ophthalmic agent.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate dihydrate
Monobasic sodium phosphate dihydrate

Sodium chloride
Sodium hydroxide for pH adjustment
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at 2°- 8°C. Do not freeze. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. Each Minims unit is overwrapped in an individual polypropylene / paper pouch. Each container holds approximately 0.5 ml of solution.

6.6 Special precautions for disposal <and other handling>

Each Minims unit should be discarded after a single use.

7. MEDICINE SCHEDULE

Prescription medicine.

8. SPONSOR

Bausch & Lomb (NZ) Ltd
c/- Corporate Services New Zealand
Level 5, 79 Queen Street
Auckland, 1010, New Zealand
Phone: 0508 443 5347

9. DATE OF FIRST APPROVAL

Date of Grant: 11.3.81
Date of Last Renewal: 16.1.97

10. DATE OF REVISION OF THE TEXT

29 September 2025

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8	Update to sponsor details