

# New Zealand Data Sheet

## 1 Prednisolone-AFT 1%

Prednisolone-AFT 1.0% w/v ophthalmic suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Prednisolone acetate (Ph Eur) 1% w/v ophthalmic suspension

For the full list of excipients, see **Section 6.1**.

## 3 PHARMACEUTICAL FORM

Prednisolone-AFT 1% is a milky white suspension for ophthalmic use.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Prednisolone-AFT 1% is indicated for the treatment of steroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

### 4.2 Dose and method of administration

**Do not shake bottle.** Instil one drop into the conjunctival sac two to four times daily. During the initial 24 to 48 hours, the dosing frequency may be increased if necessary. Care should be taken not to discontinue therapy prematurely.

If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated (see **Section 4.4**).

### Use in Children

Safety and effectiveness in paediatric patients have not been established.

### Use in the Elderly

No overall differences in safety or effectiveness have been observed between elderly and young patients.

### 4.3 Contraindications

- Most viral indications of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia and varicella
- Mycobacterial infection of the eye
- Fungal infections of ocular structures
- Tuberculosis of the eye
- Known or suspected hypersensitivity to any ingredients in the product and to other corticosteroids

#### 4.4 Special warnings and precautions for use

##### **Warnings:**

Prolonged use of corticosteroids may increase intraocular pressure in susceptible individuals resulting in glaucoma with damage to the optic nerve, defects in visual acuity, and fields of vision, and in posterior subcapsular cataract formation. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.

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 tissue may lead to perforation.

Acute untreated purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication.

Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision. If this product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.

Corticosteroids are not effective in mustard gas keratitis and Sjogren's keratoconjunctivitis.

##### **Precautions:**

**General:** The initial prescription and renewal of the prescription beyond 20 mL (2 bottles) of Prednisolone-AFT 1% should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.

If this product is used for 10 days or longer, intraocular pressure should be monitored (see **Section 4.4**).

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, consider evaluating for 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.

**Information for patients:** If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue use of the medication and consult a physician.

This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tip to the eye or to any other surface. The use of this bottle by more than one person may spread infection. Keep the bottle tightly closed when not in use. Keep out of the reach of children.

Benzalkonium chloride may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.

#### 4.5 Interaction with other medicines and other forms of interaction

The simultaneous use of Prednisolone-AFT 1% and anticholinergics e.g. atropine can magnify the corticosteroid's intraocular pressure raising effect.

This can also apply to medications which have been used recently. If other eye drops or eye ointments are also being used, a 15-minute interval should be left between instilling each preparation. Eye ointments should always be applied last.

#### 4.6 Fertility, pregnancy and lactation

##### **Pregnancy**

Category C.

In animal experiments, corticosteroids have been found to cause malformations of various kinds (cleft palate, skeletal malformations) and abortion. These findings do not seem to be relevant to humans. Reduced intrauterine growth and lower birth weight have been recorded in animals and humans after long-term or high dose treatment. Suppression of the adrenal cortex in the new-born baby, infants and children may occur after frequent long-term treatment with high dose topical steroids. The short-term use of corticosteroids prior to delivery for the prevention of respiratory distress syndrome does not seem to pose a risk to the foetus or the new-born infant.

There are no adequate and well controlled studies in pregnant women. Prednisolone-AFT 1% should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Maternal pulmonary oedema has been reported with tocolysis and fluid overload.

## **Lactation**

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from prednisolone, use is not recommended in women breast feeding infants.

### **4.7 Effects on ability to drive and use machines**

Upon instillation, patients may experience transient blurred vision which may impair the ability to drive or use machinery. If affected, patients should not drive or use machinery until their vision has cleared.

### **4.8 Undesirable effects**

#### **Eye disorders**

Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, eye penetration (scleral or corneal perforation), and delayed wound healing.

Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperaemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids.

The development of secondary ocular infection (bacterial, fungal, and viral) has occurred. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used (see Warnings and Precautions).

Transient burning and stinging upon instillation and other minor symptoms of ocular irritation have been reported with the use of Prednisolone-AFT 1%. Other adverse events reported with the use of Prednisolone-AFT 1% include: visual disturbance (blurry vision) and allergic reactions.

Urticaria, headache, dysgeusia, pruritus, and rash have also been reported.

#### **General disorders and administration site conditions**

Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticism after use of topical steroids.

#### **Reporting of suspected adverse reaction**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

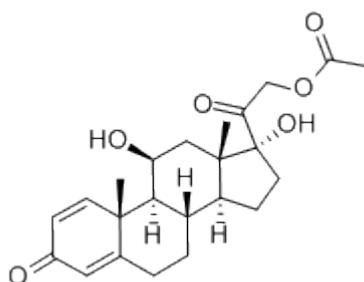
## 4.9 Overdose

Overdose by the topical ophthalmic route will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

## 5 PHARMACOLOGICAL PROPERTIES

Prednisolone acetate has the chemical name 11 $\beta$ , 17-Dihydroxy-3,20-dioxopregna-1,4-dien-21-yl acetate. It has the chemical formula C<sub>23</sub>H<sub>30</sub>O<sub>6</sub> with a molecular weight of 402.5. The CAS number is 52-21-1.



### 5.1 Pharmacodynamic properties

#### Pharmacotherapeutic group

Corticosteroid

#### ATC Code

S01BA04

Prednisolone acetate is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. Glucocorticoids inhibit the oedema, fibrin deposition, capillary dilation, and phagocytic migration of the acute inflammatory response, as well as capillary proliferation, deposition of collagen, and scar formation.

### 5.2 Preclinical safety data

#### Carcinogenesis, Mutagenesis, Impairment of Fertility:

No studies have been conducted in animals or in humans to evaluate the potential of these effects.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

- Benzalkonium chloride
- Carbomer 980
- Sodium acetate trihydrate
- Sodium hydroxide
- Sorbitol
- Water for injection

## 6.2 Incompatibilities

Not applicable

## 6.3 Shelf life

36 months

Discard any unused solution 4 weeks after opening

## 6.4 Special precautions for storage

Discard any unused product, four weeks after first opening the product.

Store below 25 °C. Do not freeze. Store in an upright position.

## 6.5 Nature and contents of container

Prednisolone-AFT 1% ophthalmic suspension is supplied sterile in LDPE dropper bottles containing 10 mL of product.

## 6.6 Special precautions for disposal

No special requirements for disposal

## 7 MEDICINE SCHEDULE

Prescription only

## 8 SPONSOR

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## 9 DATE OF FIRST APPROVAL

15 October 2015

## 10 DATE OF REVISION OF THE TEXT

20 November 2018

## SUMMARY TABLE OF CHANGES

Sections Changed	Summary of new information
All	All headings have been amended to be aligned with the updated Data Sheet requirements set by Medsafe.
All	Some sections within the Data Sheet have been moved under the appropriate headings to meet the requirements.
All	Minor changes have been implemented throughout the Data Sheet to ensure the high quality of this document.
4.4	Addition of precaution regarding visual disturbance
4.8	MedDRA SOC headings added Information relating to "reporting of suspected adverse reactions" added
4.9	Information relating to "management of overdose" added
5.1	Pharmacotherapeutic group and ATC code added
6.1	Carbomer 980 instead of Carbomer
8	More information regarding the Sponsor added
4.2	Replacement of "Shake well before using" with "Do not shake bottle."