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

Presentation
Prednisolone-AFT 1% is a milky white suspension in an eyedropper bottle for ophthalmic use. It contains 1% w/v prednisolone acetate.

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.

Dosage and 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 Warnings and Precautions).

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.

Warnings and Precautions

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 Warnings).

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.

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.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No studies have been conducted in animals or in humans to evaluate the potential of these effects.

Use in 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.

Use in 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

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.

Adverse Effects
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.

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

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.

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

Further Information

Actions
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.
Pharmacotherapeutic group S01BA04

Other
Prednisolone acetate has the chemical name 11β, 17-Dihydroxy-3,20-dioxopregna-1,4-dien-21-yl acetate. It has the chemical formula C_{23}H_{30}O_{6} with a molecular weight of 402.5. The CAS number is 52-21-1.

![Prednisolone molecule]

Prednisolone-AFT 1% also contains: sorbitol, carbomer, sodium triacetate trihydrate, sodium hydroxide, benzalkonium chloride (as preservative) and water for injections.

Pharmaceutical Precautions
Prednisolone-AFT 1% is a sterile product. Avoid touching the eye or any other surfaces with the dropper tip.

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

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

For external use only. Do not shake bottle.

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

Medicines Classification
Prescription Only Medicine
Name and Address
AFT Pharmaceuticals Ltd
PO Box 33.203
Takapuna
Auckland 0740
Tel: (09) 488 0232
Fax: (09) 488 0234

Date of Preparation
11 January 2016