1.6 Product Information

1.6.1 Summary of Product characteristics.
AUROFORT (Prednisolone Acetate USP)

1. Name of the medicinal product
AUROFORT

2. Qualitative and quantitative composition
Prednisolone acetate Ophthalmic suspension 1%w/v
For a full list of excipients, see section 6.1.

3. Pharmaceutical form
Eye drops, solution.
White color sterile suspension.

4. Clinical particulars
4.1 Therapeutic indications
For short-term treatment of steroid-responsive inflammatory conditions of the eye, after excluding the presence of viral, fungal and bacterial pathogens in adults.

4.2 Posology and method of administration
Adults:
One to two drops instilled into the conjunctival sac two to four times daily. Initially dosage may be 2 drops every hour. Care should be taken not to discontinue therapy prematurely.
Elderly patients: No adjustment in the adult dosage regimen is recommended.
Paediatric population: The safety and efficacy of Prednisolone ophthalmic suspension in paediatric patients have not yet been established. No posology can be recommended.
Method of Administration: Topical by instillation into the conjunctival sac. To reduce possible systemic absorption, it may be recommended that the lacrimal sac be compressed at the medial canthus (punctal occlusion) for 1 minute. This should be performed immediately following the instillation of each drop.

Shake well before use.

4.3 Contraindications
Acute untreated ocular infections, such as superficial (or epithelial) herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and most other viral diseases of the cornea and conjunctiva, fungal or treponemal infections of the ocular structures, mycobacterial infection such as tuberculosis of the eye

4.4 Special warnings and precautions for use
Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Employment of a corticosteroid medication in the

treatment of the patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is mandatory.
Since Prednisolone ophthalmic suspension contains no antimicrobial, if infection is present appropriate measures must be taken to counteract the organism involved.
Acute purulent untreated infection of the eye may be masked or activity enhanced by presence of steroid medication. As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid applications, fungal invasion must be suspected in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.
Eye drops containing corticosteroids should not be used for more than one week except under strict ophthalmic supervision with regular checks of intra-ocular pressure (IOP).

Prolonged use may result in elevation of IOP in susceptible individuals, resulting in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma; intraocular pressure should be checked frequently. Prolonged use may also result in posterior subcapsular cataract formation, or may aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissue, or by suppression of the host immune response. 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.
The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.
Corticosteroids are not effective in mustard gas keratitis and Sjogren's keratoconjunctivitis.
Systemic adverse events may occur with extensive use of topical steroids; punctal occlusion may be recommended.
The possibility of adrenal suppression should be considered with prolonged, frequent, use of high dose topical steroids, particularly in infants and children.
Prednisolone ophthalmic suspension contains benzalkonium chloride, which is irritant to the eye and could cause discoloration of soft (hydrophilic) contact lenses. The patient should avoid contact with contact lenses and therefore be instructed to remove them before Prednisolone ophthalmic suspension is used and then wait for at least 15 minutes before reinsertion.
To prevent eye injury or contamination, care should be taken to avoid touching the bottle tip to the eye or to any other surface.

4.5 Interaction with other medicinal products and other forms of interaction
None known.

4.6 Pregnancy and lactation

Pregnancy:

There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such defects in the human foetus. Therefore this product should be used with caution during pregnancy only if the potential benefit outweighs the potential risk to the foetus.

Breast-feeding

It is not known whether topical administration of Prednisolone Ophthalmic suspension could result in sufficient systemic absorption to produce detectable quantities in breast milk. Therefore, 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
The following undesirable effects have been reported following use of Prednisolone Ophthalmic suspension,

Immune system disorders: Not known: Hypersensitivity & Urticaria

Nervous system disorders: Not known: Headache
Eye disorders: Not known: Intraocular pressure increased, Cataract (including subcapsular)
Eye penetration (scleral or corneal perforation), Foreign body sensation Ocular hyperemia
Ocular infection (including bacterial, fungal, and viral infections), Eye irritation, Vision blurred/Visual impairment Mydriasis
Gastrointestinal disorders Not known: Dysgeusia
Skin and subcutaneous tissue disorders Not known: Pruritus, Rash
Systemic side effects may occur rarely with extensive use of topical steroids.

The possibility of adrenal suppression should be considered, particularly in infants and children.
4.9 Overdose
There is no clinical experience of overdosage. Acute overdosage is unlikely to occur via the ophthalmic route. Oral overdosage will not ordinarily cause acute problems: if accidentally ingested, patients should be advised to drink fluids to dilute.

5. Pharmacological properties
5.1 Pharmacodynamic properties

Pharmacotherapeutic group: corticosteroids, ATC code: S01BA04

Prednisolone acetate is a synthetic adrenocorticoid with the general properties of prednisolone. Adrenocorticoids diffuse across cell membranes to complex with cytoplasmic receptors and subsequently stimulate synthesis of enzymes with anti-inflammatory effects. 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.

Prednisolone acetate has, on a weight to weight basis, potency three to five times that of hydrocortisone.

5.2 Pharmacokinetic properties

Prednisolone acetate has been shown to penetrate rapidly the cornea after topical application of a suspension preparation. Aqueous humour T max occurs between 30 and 45 minutes after instillation.

The half life of prednisolone acetate in human aqueous humour is approximately 30 minutes.

5.3 Preclinical safety data

In rabbit eyes, no toxic effects were observed after application of approx. 6 mg prednisolone acetate per day over 20 days as a 1% suspension. Also, no toxic effects were observed after a single oral administration of 500 mg/kg in rats.

6. Pharmaceutical particulars

6.1 List of excipients
Hydroxy propyl methyl cellulose BP
Sodium chloride BP
Sodium citrate BP
Disodium Edetate BP
Benzalkonium chloride BP
Purified water BP

6.2 Incompatibilities

None known.

6.3 Shelf life

24months unopened.
Discard 28 days after first opening.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

5ml filled in 10ml Low density polyethylene container with HDPE cap and Nozzle. Such 10ml is packed in a monocarton with package insert.

6.6 Special precautions for disposal and other handling

There is no special requirement for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Aurolab, No.1,
Sivagangai Main road,
Veerapanjan,
Madurai - 625020,