1.6 Product Information

1.6.1 Summary of Product characteristics.
AUROPRED (Prednisolone sodium Phosphate Eye Drops BP 0.5%w/v)

1. Name of the medicinal product
AUROPRED.

2. Qualitative and quantitative composition

Each ml contains,

Prednisolone sodium phosphate	BP 0.5%w/v
Benzalkonium chloride	BP 0.01%w/v
Excipients	q.s

3. Pharmaceutical form
Eye drops, solution.
Clear colorless, free from viable particles.

4. Clinical particulars

4.1 Therapeutic indications

Non-infected inflammatory conditions of the eye.

4.2 Posology and method of administration

Posology

Adults and the elderly

One or two drops applied topically to the eye as required.

Paediatric population

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.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Care should be taken to ensure that the eye is not infected before Prednisolone sodium phosphate Eye drops 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 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 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 Prednisolone sodium phosphate Eye drops during pregnancy should be avoided.

4.7 Effects on ability to drive and use machines
Not relevant.

4.8 Undesirable effects

Eye disorders

Not known: vision, blurred (see also section 4.4)

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

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

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

4.9 Overdose

As Prednisolone sodium phosphate Eye drops are single dose units, overdose is unlikely to occur.

5. Pharmacological properties
5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, plain, ATC code: S01BA04

Mechanism of action

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.

Absorption

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

Benzalkonium Chloride
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24months

6.4 Special precautions for storage

Do not store above 30°C. Do not freeze. Keep in the original container to protect from light.

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,
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Madurai - 625020,
India.

8. Marketing authorisation number(s)

TN00002387

9. Date of first authorisation/renewal of the authorisation

11.07.2022

10. Date of revision of the text

23-01-2022