120mm

Opticort

Sterile Ophthalmic Suspension

(Prednisolone acetate)

جراثیم سے پاک آنکھوں کے قطرے

اوپٹیکورٹ

(پریڈنیسولون ایسیٹیٹ)

COMPOSITION:

Each ml contains:

Prednisolone acetate 10mg

(USP Specifications)

DESCRIPTION

OPTICORT (prednisolone acetate ophthalmic suspension) 1% is a topical anti-inflammatory agent for ophthalmic use. Prednisolone acetate is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. Prednisolone is used to treat certain types of allergies, inflammatory conditions. Some of these conditions include eye inflammation, adrenocortical insufficiency, dermatitis, asthma etc.

MODE OF ACTION

Glucocorticoids such as Prednisolone can inhibit leukocyte infiltration at the site of inflammation, interfere with mediators of inflammatory response, and suppress humoral immune responses. The anti-inflammatory actions of glucocorticoids are thought to involve phospholipase A2 inhibitory proteins, lipocortins, which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes. Prednisolone reduces inflammatory reaction by limiting the capillary dilatation and permeability of the vascular structures.

INDICATIONS

OPTICORT is indicated for the treatment of steroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, after excluding the presence of viral, fungal and bacterial pathogens in adults.

DOSAGE AND ADMINISTRATION:

Adults

One to two drops instilled into the conjunctival sac two to four times daily. During the initial 24 to 48 hours the dosing frequency may be safely increased to 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

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

Pediatric population

The safety and efficacy in pediatric population have not yet been established.

No posology can be recommended.

Method of administration

- Route of administration is by ocular instillation.
- 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.

PHARMACODYNAMIC PROPERTIES

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 edema, 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, a potency three to five times that of hydrocortisone.

PHARMACOKINETIC PROPERTIES

Prednisolone acetate has been shown to penetrate rapidly the cornea after topical application of a suspension preparation. Aqueous humor Tmax occurs between 30 and 45 minutes after installation. The half-life of prednisolone acetate in human aqueous humour is approximately 30 minutes.

WARNINGS

- Prolonged use of corticosteroids may result 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 purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication.
- 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). Employment 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 Sjögren's keratoconjunctivitis.
- Contains sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.
- **PRECAUTIONS**

General

The initial prescription and renewal of the medication order beyond 20 millilitres of OPTICORT suspension 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.

Pregnancy

Pregnancy Category C

Prednisolone has been shown to be teratogenic in mice when given in doses 1-10 times the human dose. There are no adequate well-controlled studies in pregnant women. Prednisolone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Dexamethasone, hydrocortisone, and prednisolone were ocularly applied to both eyes of pregnant mice five times per day on days 10 through 13 of gestation. A significant increase in the incidence of cleft palate was observed in the fetuses of the treated mice.

Nursing Mothers

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, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have been established.

Geriatric Use

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

ADVERSE REACTIONS:

- 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, 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 hyperemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids.
- The development of secondary ocular infection (bacterial, fungal, and viral) have occurred. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids.
- The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used.
- Transient burning and stinging upon instillation and other minor symptoms of ocular irritation have been reported with the use of OPTICORT suspension.
- Other adverse events reported with the use of OPTICORT suspension include: visual disturbance (blurry vision); foreign body sensation; and allergic reactions.

OVERDOSAGE

Overdosage will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

DRUG INTERACTIONS

None have been reported.

CONTRAINDICATIONS

OPTICORT suspension is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. Opticort suspension is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight, moisture and do not freeze.

Keep away from the reach of children. Use within one month after first opening the bottle and discard the remaining portion. Do not touch the dropper tip to any surface as this may contaminate the solution.

To be sold on the prescription of a registered medical practitioner only

SHAKE WELL BEFORE USE.

For ophthalmic use only.

HOW SUPPLIED:

5ml sterile ophthalmic Suspension in plastic dropper bottle.

خوراک و ہدایات: ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔ دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ دھوپ، گرمی، نمی، اور منجمد ہونے سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔ پہلی دفعہ بوتل کھولنے کے بعد دوا کو ایک ماہ تک استعمال کریں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549,Sundar Industrial Estate,

Lahore, Pakistan.

PM-0598-00

120mm

170mm

170mm

* Sign. Client

* Sign. Marketing Deptt. Shannza

* Sign. Designer Shannza

* for Design, Text, Size, Color & Color Placement

* Sign. Head of Design Deptt. Shannza