Summary of Product Characteristics

1. Name of the medicinal product
Pedistat eye drops.

2. Qualitative and quantitative composition
Prednisolone Acetate..... 1.0% w/v
Benzalkonium Chloride Solution(As Preservative).....0.01% w/v
Sterile Aqueous Base.....Q.s
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Milky white to off-white suspension.
Sterile single-use eye drop.

4. Clinical particulars

4.1 Therapeutic indications
Prednisolone Acetate Ophthalmic Suspension is indicated for the treatment of steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

4.2 Posology and method of administration
Posology
Shake well before using. Instill one to two drops 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 PRECAUTIONS)

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
WARNINGS
Prolonged use of corticosteroids may result in posterior subcapsular cataract formation and may increase intraocular pressure in susceptible individuals, resulting in glaucoma with damage to theoptic nerve, defects in visual acuity and fields of vision.

Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.
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. 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 ofcorticosteroid medication.
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.
Prednisolone Acetate Ophthalmic Suspension USP suspension contains sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and lifethreatening 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 milliliters of Prednisolone Acetate Ophthalmic Suspension USP 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 longterm 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.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

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

Pregnancy:

Prednisolone has been shown to be teratogenic in mice when given in doses 1-10 times the human dose. 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. 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.Nursing MothersIt 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 The safety and effectiveness in pediatric patients have been established. Use in pediatric patients is supported by evidence from adequate and well-controlled studies of prednisolone acetate ophthalmic suspension in adults with additional data in pediatric patients.

Geriatric:

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) 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).

Care should be taken to ensure that the eye is not infected before pedistat Prednisolone 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 Fertility, 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 pedistat Prednisolone during pregnancy should be avoided.

4.7 Effects on ability to drive and use machines

Prednisolone Acetate Ophthalmic Suspension USP may cause short-lasting blurring of vision upon instillation. If affected, the patient should not use machinery/electric tools or drive until vision has returned to normal.

4.8 Undesirable effects

The following adverse reactions have been identified during use of pedistat eye drops. Because reactions are reported voluntarily from a population of

uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
Adverse reactions include elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior sub capsular cataract formation, and delayed wound healing.
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 steroids.
The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used (see PRECAUTIONS).
Other adverse reactions reported with the use of prednisolone acetate ophthalmic suspension include: allergic reactions; dysgeusia; foreign body sensation; headache; pruritus; rash; transient burning and stinging upon instillation and other minor symptoms of ocular irritation; urticaria; and visual disturbance (blurry vision).Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodationand ptosis have occasionally been reported following local use of corticosteroids. Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis and perforation of the globe

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 pedistat Prednisolone, 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

As pedistat 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 solution
H.p.m.c e5
Sodium chloride
Edetate disodium
Sodium dihydrogen
Phosphate
Anhydrous disodium
Hydrogen ortho
phosphate

Hydroxypropyl
betacyclodextrin
Tween – 80
(polysorbate 80
Hydrochloric acid
Sodium hydroxide
pellets
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage

Store at temperature not exceeding 30 degrees C.Discard the solution if it changes color, turns cloudy, or if it contains particles.
Keep out of the reach of children.
Prescription only Medicine.

6.5 Nature and contents of container

The liquid is filled in a multi dose container, and contain Benzalkonium Chloride Solution, H.P.M.C E5, Edetate Disodium, Sodium Chloride, and Sodium Dihydrogen Phosphate, Anhydrous Disodium hydrogen Phosphate, Hydroxypropyl Betacyclodextrine, Tween-80, Hydrochloric Acid and Sodium Hydroxide Pellets for pH adjustment.

6.6 Special precautions for disposal and other handling
Each pedistat unit should be discarded after a single use.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder and manufacturing address:
Manufacturing address
INDIANA OPHTHALMICS
135-137, G.I.D.C Estate, Phase – II, Wadhwan City – 363035,
Surendranagar, Gujarat, India. Telephone: 91-2752-241554
Telefax: 91-2752-243939

Marketing authorization holder
(JAVIA INTERNATIONAL LTD.
c/o Arch Global Consult, The Junction Business Hub, Arsenal Branch Road, Celebasses, 2020 Mauritius.
Telephone: +230 2437888
Telefax: +230 2437889

8. Marketing authorisation number(s).
CTD10059

9. Date of first authorization.
05/07/2023

10. Date of revision of the text
17/09/2023

11. Dosimetry:
Not applicable.

12. instructions for use of radiopharmaceuticals:
Not applicable.