Summary of Product Characteristics for Pharmaceutical Products

1.Name of the medicinal product:

P-SOLON EYE DROPS (Prednisolone Acetate Ophthalmic Suspension USP 1% w/v)

2. Qualitative and quantitative composition

1% w/v prednisolone acetate.

Excipients with known effect:
Benzalkonium chloride 0.006% w/v.
Boric acid 1% w/v.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops, suspension

4. Clinical particulars

4.1 Therapeutic indications

This medication is used to treat certain eye conditions due to inflammation or injury. Prednisolone acetate works by relieving symptoms such as swelling, redness, and itching. It belongs to a class of drugs known as corticosteroids. Prednisolone Acetate Ophthalmic Suspension USP 1% w/v 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

To apply eye drops, wash your hands first. To avoid contamination, do not touch the dropper tip or let it touch your eye or any other surface. Shake the bottle well before each dose. For ophthalmic dosage form (eye drops):

- For inflammation of the eye:

Adults—Use 1-2 drops in the affected eye two to four times a day. Your doctor may tell you to use the drops more often during the first two days of treatment.

Children—Use as directed by your doctor. Tilt your head back, look upward, and pull down the lower eyelid to make a pouch. Hold the dropper directly over your eye and place 1 drop into the pouch. Look downward and gently close your eyes for 1 to 2 minutes. Place one finger at the comer of your eye (near the nose) and apply gentle pressure. This will prevent the medication from draining out. Try not to blink and do not rub your eye. Repeat these steps for your other eye if so directed and if your dose is for more than 1 drop. Apply as often as directed by your doctor. Do not rinse the dropper.

Replace the dropper cap after each use. If you are using another kind of eye medication (for example, other drops or ointments), wait at least 5 to 10 minutes before applying other medications. Use eye drops before eye ointments to allow the drops to enter the eye. Use this medication regularly in order to get the most benefit from it. To help you remember, use it at the same time(s) each day. Once opened use within 1 month.

4.3 Contraindications

Prednisolone Acetate Ophthalmic Suspension USP 1% w/v is contraindicated in acute untreated purulent ocular infections, 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. Prednisolone Acetate Ophthalmic Suspension USP 1% w/v is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

4.4 Special warnings and precautions for use

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 of corticosteroid 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.

PRECAUTIONS: General 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.

Information for Patients: Advise patients that if eye inflammation or pain persists longer than 48 hours or becomes aggravated, they should consult a physician. Advise patients that to prevent eye injury or contamination, care should be taken to avoid touching the bottle tip to eyelids or to any other surface. The use of this bottle by more than one person may spread infection. Keep bottle tightly closed when not in use. Keep out of the reach of children.

Advise patients that Prednisolone Acetate Ophthalmic Suspension USP 1% w/v contains benzalkonium chloride Solution, which may be absorbed by soft contact lenses. Contact lenses should be removed prior to application of Prednisolone Acetate Suspension USP 1% w/v and may be reinserted 15 minutes following its administration.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist can often prevent or manage interactions by changing how you use your medications or by close monitoring. 4.6 Pregnancy and

4.6 Pregnancy and Lactation

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 as directed by your doctor Nursing Mother 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 musing or to discontinue the drug, taking into account the importance of the drug to the mother. To be used as directed by your doctor.

4.7 Effects on ability to drive and use machines

Prednisolone Acetate Ophthalmic Suspension USP 1% w/v 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

Adverse reactions include elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular 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 Other adverse reactions reported with the use of prednisolone acetate ophthalmic suspension include allergic reactions; dysgeusia; eye pain; 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 accommodation and 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.

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

4.9 Overdose

Overdosage will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute. 5. Pharmacological Particulars:

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, a potency three to five times that of hydrocortisone.

5.2 Pharmacokinetic properties

Absorption: After ophthalmic use, absorbed through aqueous humour. Systemic absorption rarely occurs. Distribution: After ophthalmic use, distributed throughout local tissue layers. Any drug absorbed into circulation is rapidly removed from blood and distributed into muscle, liver, skin, intestines, and kidneys. Metabolism: After ophthalmic use, corticosteroids primarily metabolized locally. Small amount absorbed into systemic circulation is metabolized primarily in liver to inactive compounds. Excretion: Inactive metabolites excreted by kidneys, primarily as glucuronides and sulfates, but also as unconjugated products. Small amounts of metabolites excreted in faeces.

5.3 Pre-clinical Safety data

Non-clinical data reveal no special hazard for humans based on conventional studies on the acute toxic potential of Prednisolone Acetate Ophthalmic Suspension.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium chloride Solution
Borax
Boric Acid
Disodium EDTA
Tween 80
Glycerin
Hydroxypropylmethylcellulose
Sodium Chloride
Water for Injections

6.2 Incompatibilities

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

Prednisolone Acetate Ophthalmic Suspension is filled in 5 ml white colour plastic bottle with cap and packed in a carton and pack insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder

GALAXY PHARMACEUTICAL LIMITED
P.O. BOX 39107-00623, NAIROBI

8. Marketing authorization number(s)

H2022/CTD8396/17826

9. Date of first authorization/renewal of the authorization

2022 January 11

10. Date of revision of the text

August 2019