Summary of Product Characteristics
PRED FORTE
(Prednisolone acetate 10 mg/mL eye drops, suspension)

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1. Name of the medicinal product

Pred Forte Sterile Eye Suspension (Prednisolone Acetate 10 mg/mL Eye Drops, Suspension)

2. Qualitative and quantitative composition

1 mL of suspension contains 10 mg of prednisolone acetate (1% w/v).

Excipient with known effect:
This medicine contains benzalkonium chloride.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Eye drops, suspension.

4. Clinical particulars

4.1 Therapeutic indications

Pred Forte is indicated for the treatment of steroid-responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, and selected infective conjunctivitis when the inherent hazard of steroid use is accepted to obtain an advisable diminution in oedema and inflammation. It is also indicated for the treatment of corneal injury from chemical, radiation or thermal burns, or penetration of foreign bodies.

4.2 Posology and method of administration

Posology

Adults (including the elderly): instil one to two drops into the conjunctival sac of the affected eye(s) two to four times daily. During the initial 24 to 48 hours the frequency of dosing may be increased if necessary. Care should be taken not to discontinue therapy prematurely. Treatment should be reviewed regularly, and prolonged use should be avoided (see section 4.4).

Paediatric population

Safety and efficacy in children have not been established; use in children should be under specialist supervision.

Method of administration

For ocular use only. Shake well before use. To avoid contamination, the dropper tip should not touch any surface or the eye. If more than one topical ophthalmic product is used, the medicines should be administered at least 5 minutes apart. Contact lenses should be removed before instillation and not reinserted for at least 15 minutes.

4.3 Contraindications

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

- Acute untreated purulent ocular infections, which corticosteroids may mask or enhance.
- Epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella and most other viral diseases of the cornea and conjunctiva.
- Mycobacterial ocular infection and fungal diseases of ocular structures.

4.4 Special warnings and precautions for use

Prolonged use of topical ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve and defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Intra-ocular pressure should be monitored routinely, particularly where treatment is continued beyond 10 days.

In diseases causing thinning of the cornea or sclera, perforation has been known to occur with topical corticosteroids. In acute purulent conditions, corticosteroids may mask infection or enhance existing infection. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections, including fungal and viral infections of the cornea; fungal invasion should be considered in any persistent corneal ulceration where a corticosteroid has been used. Use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation. The initial prescription and renewal beyond 14 days should be made by an ophthalmologist.

Benzalkonium chloride

This medicine contains benzalkonium chloride, which may cause eye irritation and is known to discolour soft contact lenses; contact with soft contact lenses should be avoided. It has also been reported to cause punctate keratopathy and/or toxic ulcerative keratopathy, and monitoring is required with frequent or prolonged use.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems. Given the low systemic exposure following topical ocular administration, clinically relevant systemic interactions are unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of prednisolone eye drops in pregnant women. Prolonged or repeated corticosteroid use during pregnancy has been associated with an increased risk of intra-uterine growth retardation. Pred Forte should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus, at the lowest effective dose for the shortest possible time.

Breast-feeding

Systemically administered corticosteroids are excreted in breast milk; it is unlikely that topical ocular administration would result in detectable quantities in milk. Caution should nevertheless be exercised.

4.7 Effects on ability to drive and use machines

As with other eye drops, transient blurred vision or other visual disturbances on instillation may affect the ability to drive or use machines; the patient should wait until vision clears before driving or using machines.

4.8 Undesirable effects

The adverse reactions are listed below by System Organ Class and frequency, defined as: common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Immune system disorders	Not known	Hypersensitivity
Endocrine disorders	Not known	Cushingoid features and adrenal suppression following prolonged intensive use
Eye disorders	Common	Ocular discomfort, transient blurred vision on instillation
	Uncommon	Increased intra-ocular pressure
	Not known	Glaucoma with optic-nerve damage, posterior subcapsular cataract, delayed wound healing, secondary ocular infection (bacterial, fungal or viral, including herpes simplex reactivation), corneal or scleral thinning and perforation, mydriasis, ptosis, eye pain, foreign-body sensation
General disorders and administration site conditions	Not known	Application-site irritation

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 to the National Regulatory Authority.

4.9 Overdose

An ocular overdose may be flushed from the eye(s) with lukewarm water. Acute overdose by topical ocular administration is unlikely to cause systemic effects; in the event of accidental ingestion, treatment is symptomatic and supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals, anti-inflammatory agents, corticosteroids, plain. ATC code: S01BA04.

Prednisolone acetate is a synthetic glucocorticoid with marked anti-inflammatory activity. Applied topically to the eye, it suppresses the inflammatory response to a variety of inciting agents of mechanical, chemical or immunological nature, inhibiting oedema, fibrin deposition, capillary dilatation, leucocyte migration, capillary and fibroblast proliferation, deposition of collagen and scar formation. (Note: the pharmacotherapeutic classification recorded as ‘ophthalmological anti-infective/sulfonamide’ in the registration database is incorrect for this product, which is an ophthalmic corticosteroid.)

5.2 Pharmacokinetic properties

Following topical ocular administration, prednisolone acetate penetrates the cornea and is absorbed into the ocular tissues. Systemic absorption is low; any absorbed prednisolone is metabolised in the liver and excreted in the urine as conjugated and unconjugated metabolites.

5.3 Preclinical safety data

Prednisolone is a well-established corticosteroid. Non-clinical data reveal no special hazard for humans at clinically relevant topical exposures beyond that reflected in other sections of this Summary of Product Characteristics; as with other corticosteroids, systemic administration of high doses in animals produced effects consistent with exaggerated glucocorticoid activity.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium chloride (preservative). The full quantitative list of the remaining excipients (which for this suspension typically includes hypromellose, polysorbate 80, sodium chloride, sodium

citrate, citric acid, disodium edetate, sodium hydroxide and/or hydrochloric acid for pH adjustment, and purified water) should be confirmed verbatim from the applicant's finished-product formulation (3.2.P.1).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

To be confirmed from the applicant's stability data. After first opening, the contents should be used within 28 days.

6.4 Special precautions for storage

Store upright, below 25°C. Do not freeze. Protect from light. Keep out of the reach and sight of children.

6.5 Nature and contents of container

Plastic dropper bottle (LDPE bottle with dropper tip and polystyrene cap) containing the suspension, presented in a carton with the package insert.

6.6 Special precautions for disposal and other handling

Shake well before use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Allergan Pharmaceuticals (Pty) Ltd.

Manufacturer

Allergan Pharmaceuticals (Ireland), Ireland.

8. Marketing Authorisation Number

H2009/5977/R1

9. Date of first authorisation / renewal of the authorisation

10. Date of revision of the text