Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pred Forte 1% w/v, Eye Drops Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Prednisolone acetate 1.0 % w/v.

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 (eye drops)
A dense white sterile microfine eye drops suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For short-term treatment of steroid-responsive inflammatory conditions of the eye, after excluding the presence of viral, fungal and bacterial pathogens in adults.

4.2 Posology and method of administration

Posology

Adults
One to two drops instilled into the conjunctival sac two to four times daily. Initially dosage may be 2 drops every hour. Care should be taken not to discontinue therapy prematurely.

Elderly patients
No adjustment in the adult dosage regimen is recommended.

Paediatric population
The safety and efficacy of Pred Forte in paediatric patients have not yet been established. No posology can be recommended.

Method of Administration

Topical by instillation into the conjunctival sac.

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.

4.3 Contraindications

Acute untreated ocular infections, such as superficial (or epithelial) herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, and most other viral diseases of the cornea and conjunctiva, fungal or treponemal infections of the ocular structures, mycobacterial infection such as tuberculosis of the eye.

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

4.4 Special warnings and precautions for use

Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of the patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is mandatory.

Since Pred Forte contains no antimicrobial, if infection is present appropriate measures must be taken to counteract the organism involved.

Acute purulent untreated infection of the eye may be masked or activity enhanced by presence of steroid medication. As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid applications, fungal invasion must be suspected in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

Eye drops containing corticosteroids should not be used for more than one week except under strict ophthalmic supervision with regular checks of intra-ocular pressure (IOP).

Prolonged use may result in elevation of IOP in susceptible individuals, resulting in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma; intraocular pressure should be checked frequently. Prolonged use may also result in posterior subcapsular cataract formation, or may aid in the establishment of secondary ocular infections from fungi or viruses liberated from ocular tissue, or by suppression of the host immune response. 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.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Corticosteroids are not effective in mustard gas keratitis and Sjogren's keratoconjunctivitis.

Systemic adverse events may occur with extensive use of topical steroids; punctal occlusion may be recommended (see Section 4.2).

The possibility of adrenal suppression should be considered with prolonged, frequent, use of high dose topical steroids, particularly in infants and children.

Pred Forte contains benzalkonium chloride, which is irritant to the eye and could cause discoloration of soft (hydrophilic) contact lenses. The patient should avoid contact with contact lenses and therefore be instructed to remove them before Pred Forte is used and then wait for at least 15 minutes before reinsertion.

Pred Forte contains boron and should not be used in children less than 12 years old because of safety concerns over impairment of fertility.

To prevent eye injury or contamination, care should be taken to avoid touching the bottle tip to the eye or to any other surface.

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 interactions

None known.

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

Pregnancy

There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such defects in the human foetus. Therefore this product should be used with caution during pregnancy only if the potential benefit outweighs the potential risk to the foetus.

Breast-feeding

It is not known whether topical administration of Pred Forte could result in sufficient systemic absorption to produce detectable quantities in breast milk. Therefore, use is not recommended in women breast feeding infants.

4.7 Effects on ability to drive and use machines

Upon instillation, patients may experience transient blurred vision which may impair the ability to drive or use machinery. If affected, patients should not drive or use machinery until their vision has cleared.

4.8 Undesirable effects

The following undesirable effects have been reported following use of Pred Forte.

Frequency categories: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from available data).

Immune system disorders
Not known: Hypersensitivity
Urticaria

Nervous system disorders
Not known: Headache

Eye disorders
Not known: Intraocular pressure increased*****
Cataract (includingsubcapsular)*
Eye penetration (scleral or corneal perforation) *****
Foreign body sensation
Ocular hyperemia
Ocular infection (including bacterial*, fungal*, and viral* infections)
Eye irritation
Eye pain
Vision blurred*/Visual impairment
Mydriasis

Gastrointestinal disorders
Not known: Dysgeusia

Skin and subcutaneous tissue disorders
Not known: Pruritus
Rash

Systemic side effects may occur rarely with extensive use of topical steroids.*

The possibility of adrenal suppression should be considered, particularly in infants and children.*

* See Section 4.4 for further information.

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:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

4.9 Overdose

There is no clinical experience of overdosage. Acute overdosage is unlikely to occur via the ophthalmic route. Oral overdosage will not ordinarily cause acute problems: if accidentally ingested, patients should be advised to drink fluids to dilute.

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

Prednisolone acetate has been shown to penetrate rapidly the cornea after topical application of a suspension preparation. Aqueous humour T_{max} occurs between 30 and 45 minutes after instillation.

The half life of prednisolone acetate in human aqueous humour is approximately 30 minutes.

5.3 Preclinical safety data

In rabbit eyes, no toxic effects were observed after application of approx. 6 mg prednisolone acetate per day over 20 days as a 1% suspension. Also, no toxic effects were observed after a single oral administration of 500 mg/kg in rats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride
Hypromellose
Polysorbate 80
Boric Acid
Sodium Citrate
Sodium Chloride
Disodium Edetate
Hydrochloric Acid or
Sodium Hydroxide
(for pH adjustment)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 2 years.
Opened: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Bottles and dropper tips composed of low density polyethylene containing either 5 ml or 10 ml of Pred Forte, Eye Drops Suspension. Screw caps are medium impact polystyrene.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

AbbVie Limited
Citywest Business Campus
Co Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1824/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

April 2022