# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Pred Forte 1% w/v, Eye Drops Suspension

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1% w/v prednisolone acetate.
Excipient(s) with known effect: Benzalkonium chloride 0.006% w/v.
For the full list of excipients, see section 6.1.

# 3 PHARMACEUTICAL FORM

Eye drops, suspension.
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. 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.

*Paediatric population*
The safety and efficacy in paediatric 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.

## 4.3 CONTRAINDICATIONS

Acute untreated purulent ocular infections. Acute superficial herpes simplex (dendritic keratitis); vaccinia, varicella and most other viral diseases of the cornea and conjunctiva. Fungal diseases of the eye. 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

Acute purulent infections of the eye may be masked or enhanced by the use of topical steroids. Pred Forte contains no antimicrobial agent. If infection is present, appropriate measures must be taken to counteract the infective organisms.

Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.

Fungal infections of the cornea have been reported coincidentally with long-term steroid application and fungal invasion may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use.

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal or scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.

The preservative in Pred Forte, benzalkonium chloride, may be absorbed by and cause discoloration of soft contact lenses. Patients wearing soft contact lenses should be instructed to remove contact lenses prior to administration of the solution and wait at least 15 minutes after instilling Pred Forte before reinserting soft contact lenses.
Use of intraocular steroids may prolong the course and may exacerbate the severity of many viral infections on the eye (including herpes simplex). Patients with a history of herpes simplex keratitis should be treated with caution. Use of steroid medication in the presence of stromal herpes simplex requires caution and should be followed by frequent, mandatory, slit-lamp microscopy.

Prolonged use of topical corticosteroids may cause an increase in intraocular pressure in certain individuals. This may result in glaucoma with damage to the optic nerve with resultant defects in visual acuity and visual fields. Steroids should be used with caution in the presence of glaucoma. It is advisable that intraocular pressure be checked frequently during treatment with Pred Forte.

Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure.

Posterior subcapsular cataract formation has been reported after heavy or protracted use of topical ophthalmic corticosteroids.

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

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.

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 INTERACTION

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

Pred Forte 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 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 (including subcapsular)*
Eye penetration (scleral or corneal perforation)*
Foreign body sensation
Ocular infection (including bacterial*, fungal*, and viral* infections)
Ocular stinging
Eye irritation
Eye pain
Ocular hyperemia
Vision blurred* /Visual impairment
Mydriasis

*Gastrointestinal disorders*
Not known: Dysgeusia

*Skin and subcutaneous tissue disorders*
Not known: Pruritus, Rash

Systemic: extensive topical use of corticosteroids may lead to systemic side effects*.

* 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:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

### 4.9. Overdose

There is no clinical experience of overdosage. Acute overdosage is unlikely to occur via the ophthalmic route.

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

### 5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies on the acute toxic potential of Pred Forte.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. List of excipients

Benzalkonium chloride
Hydroxypropylmethylcellulose
Polysorbate 80
Boric acid
Sodium citrate
Sodium chloride
Disodium edetate
Purified water.

## 6.2 INCOMPATIBILITIES

None known.

### 6.3 Shelf life

2 years unopened.
28 days after first opening.

## 6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25 C. Do not freeze.

### 6.5 Nature and contents of container

5 ml and 10 ml bottles and dropper tips composed of low density polyethylene. Screw caps are medium impact polystyrene.

Not all pack sizes may be marketed.

## 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements.

# 7 MARKETING AUTHORISATION HOLDER

Allergan Ltd
Marlow International
The Parkway
Marlow
Bucks
SL7 1YL
UK

## 8. MARKETING AUTHORISATION NUMBER(S)

PL 00426/0051

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

3rd March 1988 / 19th March 1998

# 10 DATE OF REVISION OF THE TEXT

14/01/2019