

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Prednisolon mibe 10 mg/ml eye drops, suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml eye drops suspension contains 10 mg prednisolone acetate.

Excipients with known effect:

1 ml eye drops suspension contains 0.06 mg benzalkonium chloride and 10 mg boric acid.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, suspension.

White or almost white, microfine suspension (pH 5.5 to 6.0, 260 to 350 mOsmol/kg).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prednisolon mibe is used in adults for the short-term, symptomatic treatment of severe, non-infectious inflammatory diseases of the anterior part of the eye, e.g. anterior uveitis, attenuation of postoperative inflammatory symptoms, e.g. following cataract surgery.

4.2 Posology and method of administration

Posology

It is recommended that 1 drop be instilled 4 times daily into the conjunctival sac of the eye. If needed, the dosing frequency may be increased to hourly dosing during the first 24 - 48 hours and should thereafter be slowly decreased in the following days or weeks.

To ensure the therapeutic effect, treatment should not be discontinued prematurely. Treatment with corticosteroids should generally not exceed a duration of 4 weeks (see section 4.4). Uncontrolled prolonged use must be avoided.

If no improvement occurs within two days after the start of treatment, the indication should be re-examined (see also sections 4.3 and 4.4.).

Paediatric population

The safety and efficacy of Prednisolon mibe in children have not yet been established.

The lowest possible dose should be used. Long-term treatment should be avoided in children (see section 4.4.).

Method of administration

When opening the bottle for the first time please shake the bottle 10 times.

Please shake the bottle vigorously before use.

In order to reduce possible systemic absorption, it is recommended that the lacrimal sac at the medial canthus be compressed (punctal occlusion) for 1 minute or gently closing the eyelid immediately after instillation. Excess overflow should be immediately cleaned from the face.

If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart.

4.3 Contraindications

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

Acute herpes simplex (dendritic keratitis) and other viral eye infections.

Acute bacterial and fungal eye infections without adequate antibiotic treatment.

Narrow-angle and advanced glaucoma which cannot be adequately controlled by medicinal products alone.

4.4 Special warnings and precautions for use

Acute purulent eye infections can be masked by the use of Prednisolon mibe or even exacerbated by use of the corticosteroid. As Prednisolon mibe contains no antimicrobial active substance, appropriate measures to combat pathogens must be taken in the presence of an infection.

Corneal fungal infections have been reported coincidentally with long-term local steroid application and fungal invasion may be suspected in any persistent corneal ulceration where a steroid has been used, or is in use. In such cases, samples should be taken.

The use of corticosteroids can lead to aggravation or outbreak of viral eye infections (including herpes simplex). The use of eye drops containing cortisone should therefore be carefully monitored in patients with a history of herpes simplex infection (see also section 4.3).

After prolonged use, there may be a rise in intraocular pressure in predisposed patients (e.g. patients with Diabetes mellitus), with possible development of glaucoma with damage to the optic nerve with visual fields defects. Regular monitoring of intraocular pressure is therefore recommended. Especially when using the medicine for 10 days or more, the intraocular pressure and cornea should be regularly monitored. This is especially important in paediatric patients receiving prednisolone-containing products, as the risk of steroid-induced ocular hypertension may be greater in children below 6 years of age and may occur earlier than a steroid response in adults.

Posterior subcapsular cataract formation has been reported after long-term use of topical ophthalmic corticosteroids.

Eye drops containing corticosteroids may slow down wound healing especially after prolonged use and at higher concentrations. The use of steroids after cataract surgery can delay healing and increase the incidence of bleb formation.

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal or scleral thinning with a risk for perforation.

Following intensive use of topical steroids, undesirable systemic effects can occur. Punctal occlusion is recommended (see section 4.2).

During prolonged, high-dose use of topical steroids, the possibility of adrenal suppression should be considered, especially 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.

Preservative

Prednisolone mibe contains benzalkonium chloride, which is commonly used as a preservative in ophthalmic products.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.

Patients should be monitored in case of prolonged use.

Contact lenses

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Patients must remove contact lenses before using this medicine and put them back 15 minutes afterwards.

This medicine contains boric acid

This medicine should not be given to a child younger than 12 years without medical advice, as it contains boron and may impair fertility in the future.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions have been reported to date. An additional increase in intraocular pressure cannot be excluded if eye drops containing cortisone are co-administered with substances such as atropine or other anticholinergic agents that can also increase intraocular pressure in predisposed patients.

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 intrauterine 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.

Breastfeeding

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

4.7 Effects on ability to drive and use machines

After instillation, the patient may temporarily experience blurred vision, which could impair the ability to drive or use machines. Affected patients may not drive or use machines until their sight is clear again.

4.8 Undesirable effects

The following undesirable effects are listed without frequency information. The frequency cannot be estimated from the available data.

Immune system disorders
hypersensitivity, urticaria.

Nervous system disorders
headache.

Eye disorders
intraocular pressure increased*, cataract (including subcapsular)*, penetration injury of the eye (scleral or corneal perforation)*, foreign body sensation in the eye, ocular infection (including bacterial, fungal and viral eye infection)*, eye irritation, hyperaemia of the eye, eye pain, blurred vision*/reduced vision, mydriasis, eyelid ptosis**.

Gastrointestinal disorders
dysgeusia.

Skin and subcutaneous tissue disorders
pruritus, exanthem.

* See section 4.4 for further information.

** Reported in connection with long term treatment.

Substance class-specific undesirable effects:

Furthermore, eye drops containing corticosteroids such as Prednisolon mibe have, in rare cases ($\geq 1/10\ 000$ to $< 1/1\ 000$), been reported to cause the following undesirable effects:

- keratitis
- corneal ulcers.

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 the national reporting system:

<to be completed nationally>.

4.9 Overdose

There is no clinical experience of overdosage. Acute overdosage is unlikely to occur via the ophthalmic route. If necessary, rinse eye thoroughly with water. After accidental ingestion, drinking plenty of liquid for dilution is sufficient.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ophthalmologicals – antiinflammatory agents – corticosteroids, plain.
ATC code: S01BA04

Prednisolone acetate is a synthetic glucocorticosteroid, which exerts an anti-inflammatory effect approximately 4 times more potent than hydrocortisone. It prevents the release of prostaglandins and leukotrienes, which are inflammatory mediators, by inhibiting arachidonic acid synthesis. As a result, it antagonises acute inflammatory manifestations, such as oedema, fibrin deposition, vasodilation, phagocytic migration, collagen deposition and scarring.

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 minutes and 2 hours after instillation. The half-life of prednisolone acetate in human aqueous humour has been estimated to approximately 30 minutes.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies to investigate the acute toxic potential of Prednisolon mibe.

Study findings available for glucocorticoids reveal no indications of clinically relevant, genotoxic properties.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Boric acid
Sodium citrate
Sodium chloride
Hypromellose
Polysorbate 80
Sodium edetate
Benzalkonium chloride
Sodium hydroxide solution or hydrochloric acid solution for pH adjustment
Water for injections.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

In the unopened container: 3 years.
After opening: 4 weeks.

6.4 Special precautions for storage

Do not store above 25 °C.
Keep the dropper container in the outer carton, in order to protect from light.
Store upright to avoid clogging of the dropper tip.

6.5 Nature and contents of container

LDPE bottle with LDPE dropper applicator and HDPE tamper-proof screw cap.
Each bottle contains 5 ml eye drops suspension.

Pack sizes:

1 x 5 ml
2 x 5 ml
3 x 5 ml and
6 x 5 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

<to be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

<to be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

<to be completed nationally>

10. DATE OF REVISION OF THE TEXT

2025-12-19