

SUMMARY PRODUCT CHARACTERISTIC (SPC)

1.1 NAME OF THE MEDICINAL PRODUCT – Hydrocortisone eye ointment 5 mg/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

active ingredient: Hydrocortisone acetate – 5 mg

Contains methylparaben.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.

White or almost white translucent unctuous mass with a slight smell of ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Allergic eye diseases (blepharitis, eyelids dermatitis, conjunctivitis, keratoconjunctivitis)
- Inflammatory diseases of the eye anterior section in the absence of violations of the integrity of the corneal epithelium (conjunctivitis, keratoconjunctivitis, blepharitis)
- Chemical and thermal eye burns (after corneal defects complete healing).

4.2 Posology and method of administration

For topical administration.

1-2 cm ribbon of ointment should be placed inside the lower conjunctival sac 2-3 times daily for 1-2 weeks.

Do not use for more than 1-2 weeks without consulting a doctor.

4.3 Contraindications

- Vaccinia, varicella, or other viral diseases of cornea and conjunctiva
- Ocular herpes simplex
- Fungal diseases of ocular structures
- Mycobacterial ocular infections
- Acute, untreated purulent bacterial infections
- Hypersensitivity to hydrocortisone or to any of the excipients.
- Intraocular tuberculosis
- Glaucoma
- Trachoma
- Vaccination
- Eye injury

- Children under 18 years of age

With caution

Pregnancy and lactation

4.4 Special warnings and precautions for use

For ocular use only.

Contact lens wear is not recommended during treatment of an ocular inflammation.

There is no evidence of safety in use in children under two years of age.

The time interval between the topical instillation of eye drops and ointment should not be less than 15 minutes in simultaneous application.

In patients receiving prolonged ophthalmic corticosteroid therapy (more than 10 days), intraocular pressure should be checked, particularly in patients with a history or presence of open-angle or angle-closure glaucoma.

May cause transient blurring of vision on applying of the ointment. User should not drive or operate hazardous machinery unless vision is clear.

Do not use after the expiration of date.

4.5 Interaction with other medicinal products and other forms of interaction

It is well known that prolonged use topically applied Hydrocortisone can be absorbed percutaneously. It is likely to cause systematic effects like: reduction of the effectiveness of insulin, oral hypoglycemic medications, hypertension medications, anticoagulants, plasma concentration of praziquantel and salicylates.

The risk of side effects of hydrocortisone increases: androgens, estrogens, oral contraceptives, anabolic steroids (hirsutism, acne), antipsychotic drugs, carbutamidum, azathioprine (cataracts), cholinergic blockers, antihistamine drugs, tricyclic antidepressants, nitrates (glaucoma), diuretics (hypoglycemia).

Simultaneous intake of cardiac glycosides and hydrocortisone may result enhancement of digitalis toxicity.

Simultaneous use of Hydrocortisone and silver and lead preparations will result mutual inactivation.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established.

There is no inadequate evidence that the topical use of glucocorticoid does pass into breast milk, however the risk should not be excluded.

To be used in pregnancy and lactation unless the therapeutic benefit is expected to outweigh the potential risk to the child or fetus.

The duration of treatment in this case should not be more than 7-10 days.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision on instillation or sensitivity to bright light.

Warn patients not to drive or use hazardous machinery if vision is not clear.

4.8 Undesirable effects

Viral and fungal infections may be exacerbated by corticosteroids. Topical corticosteroids may induce scleral or corneal perforation.

Allergic reaction, burning, transient blurring of vision, redness.

Prolonged use (more than 10 days) may result in ocular hypertension and/or steroid glaucoma, with damage to the optic nerve, visual field defects (in patients receiving

prolonged ophthalmic corticosteroid therapy (more than 10 days), intraocular pressure should be checked routinely), and posterior subcapsular cataract formation. Topical ophthalmic corticosteroids may slow corneal wound healing. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.

Corticosteroids may reduce resistance to and aid in the establishment of bacterial, and fungal infections and mask the clinical signs of infections, preventing recognition of ineffectiveness of the antibiotic

Fungal infection should be suspected in patients with persistent corneal ulceration who has been or are receiving glucocorticoid for a long time, and corticosteroids therapy should be discontinued if fungal infection occurs.

4.9 Overdose

Long-term intensive topical use may lead to systemic effects. An ocular overdose of Hydrocortisone can be flushed from the eye(s) with lukewarm water.

Hydrocortisone eye ointment overdose cases are rare.

Symptoms: local side effects are possible.

If Hydrocortisone is withdrawn the symptoms of overdose pass automatically.

5. PHARMACOLOGICAL ACTION

5.1 Pharmacodynamic properties

ATC code: S01BA02

Pharmacotherapeutic Group: Corticosteroids.

Corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions. Short-acting glucocorticoid that depresses formation, release, and activity of endogenous mediators of inflammation including prostaglandins, kinins, histamine, liposomal enzymes, and complement system.

Hydrocortisone is a corticosteroid with both glucocorticoid and to a lesser extent mineralocorticoid activity. As cortisol it is the most important of the predominantly glucocorticoid steroids secreted by the adrenal cortex. Hydrocortisone is used, usually with a more potent mineralocorticoid, for replacement therapy in adrenocortical insufficiency. It may also be used for its glucocorticoid properties in other conditions for which corticosteroid therapy is indicated but drugs with fewer mineralocorticoid effects tend to be preferred for the long-term systemic therapy of auto-immune and inflammatory disease.

Thus, in addition to the elimination of inflammation and pruritis, a normalisation of keratinisation, inhibition of excess fibroblast activity and epidermopoiesis, degradation of pathological metabolic products and inhibition of acantholysis are achieved.

5.2 Pharmacokinetic properties

Absorption

Hydrocortisone hardly penetrates into intraocular fluid through the cornea.

Sufficient absorption may occur after topical application to the epidermis and the mucous membranes of the eyes to produce systemic effects.

Metabolism

After topical administration, hydrocortisone is metabolized primarily in the epidermis and the mucous membranes of the eyes. The small amount absorbed into systemic circulation is metabolized primarily in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol.

Metabolism is similar to other corticosteroids. Intraocular penetration occurs and contributes to the effectiveness of hydrocortisone in anterior segment inflammatory disease. Hydrocortisone circulates in the blood with 80% bound to transcortin and 10% to albumin.

Excretion:

Inactive metabolites are excreted by the kidneys, primarily as glucuronides and sulfates, but also as unconjugated products. Small amounts of metabolites are also excreted in feces.

5.3 Preclinical safety data

Preclinical data reaffirms the safety of the drug.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylparaben

Paraffin white soft

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

After opening, the tube can be stored for 28 days.

6.4 Special precautions for storage

Store at a temperature below 15 °C, protected from light and moisture. Keep out of reach of children.

6.5 Nature and contents of container

3 g of eye ointment into aluminium tubes. The tubes are packed and inserted with the leaflet into cardboard boxes.

6.6 Special precautions for disposal and other handling

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

7. MARKETING AUTHORIZATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

№15866

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