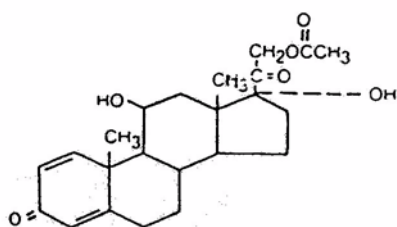


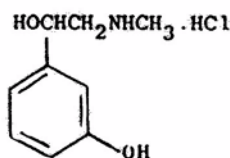
PREDNEFRIN® FORTE Eye Drops

NAME OF THE DRUG

The active constituents of PREDNEFRIN® FORTE eye drops are prednisolone acetate and phenylephrine hydrochloride.



Structure of prednisolone acetate



Structure of phenylephrine hydrochloride

DESCRIPTION

Prednisolone acetate is an odourless, white or almost white, crystalline powder. Practically insoluble in water, soluble 1 in 120 of alcohol; slightly soluble in acetone and chloroform. MW: 402.5.

Chemical Name: 11 β ,17 α ,21-trihydroxypregna-1,4-diene-3,20-dione.

Empirical formula: C₂₁H₂₈O₅

Phenylephrine hydrochloride is white or almost white, odourless crystals or crystalline powder. Soluble 1 in 2 of water, and 1 in 4 of alcohol; practically insoluble in chloroform. MW: 203.7.

Chemical Name: (*R*)-3-hydroxy- α -[(methylamino)methyl]benzenemethanol hydrochloride.

Empirical formula: C₉H₁₄ClNO₂

PREDNEFRIN® FORTE eye drops contain prednisolone acetate (microfine suspension) 10 mg (1%), phenylephrine hydrochloride 1.2 mg (0.12%), benzalkonium chloride 0.04 mg (0.004%) per 1 mL, with hypromellose, phenazone, polysorbate 80, boric acid, sodium citrate, sodium metabisulfite, sodium chloride, disodium edetate and purified water.

PHARMACOLOGY

Prednisolone acetate is a glucocorticoid that, on the basis of weight, has 3 to 5 times the anti-inflammatory potency of hydrocortisone. 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. The phenylephrine component of PREDNEFRIN® FORTE eye drops constricts the engorged vessels of the eye and lid.

INDICATIONS

Severe inflammation (non-infectious) of the eye, such as acute iritis, iridocyclitis, scleritis, episcleritis, uveitis, resistant ocular allergy and inflammation following surgery (where no infectious aetiology is suspected), particularly where unusually rapid control of the inflammation is desired.

CONTRAINDICATIONS

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

Hypersensitivity to prednisolone acetate, phenylephrine hydrochloride, benzalkonium chloride or any of the other constituents.

PRECAUTIONS

In diseases due to microorganisms, acute untreated infection may be masked, enhanced or activated by the steroid. Since PREDNEFRIN[®] FORTE is not an anti-infective, if infection is present, appropriate measures must be taken to counteract the organisms involved. As fungal infections of the cornea are particularly prone to develop with long-term local steroid application, 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. Use of intraocular steroid medication in the presence of stromal *Herpes simplex* may prolong the course and may exacerbate the severity of many viral infections of the eye. Use of corticosteroid medication in the treatment of patients with a history of *Herpes Simplex* requires caution and should be followed by frequent mandatory slit-lamp microscopy (please refer to "Contraindications"). PREDNEFRIN[®] FORTE eye drops contains benzalkonium chloride as a preservative.

Eye drops containing corticosteroids should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for intraocular pressure. Extended use of topical corticosteroids may cause increased intraocular pressure in susceptible individuals resulting in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision. Prolonged use may result in posterior subcapsular cataract formation. PREDNEFRIN[®] FORTE eye drops should be used with caution in the presence of narrow angle glaucoma.

In diseases causing thinning of the cornea, perforation has been known to have occurred with the use of topical steroids. Reports in the literature indicate that posterior subcapsular lenticular opacities have been reported to occur after heavy or protracted use of topical ophthalmic corticosteroids.

PREDNEFRIN[®] FORTE eye drops contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. Sulfite sensitivity is seen more frequently in asthmatic patients.

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

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

Use in Children

There are no adequate and well controlled studies in pediatric patients.

Information for patients: 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.

Use in pregnancy: Category C. In animal experiments, corticosteroids have been found to cause malformations of various kinds (cleft palate, skeletal malformations) and abortion. These findings do not seem to be relevant to humans. Reduced intrauterine growth and lower birth weight have been recorded in animals and humans after long-term or high dose treatment. Suppression of the adrenal cortex in the newborn baby may occur after long-term treatment. The short-term use of corticosteroids prior to delivery for the prevention of respiratory distress syndrome, does not seem to pose a risk to the fetus or the newborn infant.

There are no adequate and well controlled studies in pregnant women. PREDNEFRIN FORTE[®] should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Maternal pulmonary oedema has been reported with tocolysis and fluid overload.

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

ADVERSE REACTIONS

Adverse reactions include increased intraocular pressure, which may be associated with optic nerve damage and defects in the visual fields; posterior subcapsular cataract formation; eye penetration (sclera or corneal perforation), ocular infections from bacteria, fungi or viruses liberated from ocular tissues and perforation of the globe when used in conditions where there is thinning of the cornea or sclera, eye irritation, vision blurred/visual disturbances and mydriasis.

Other non-ocular adverse reactions seen include: hypersensitivity, urticaria, headache, dysgeusia, pruritus and rash. Systemic side effects may occur rarely with extensive use of topical steroids.

OVERDOSAGE

Overdosage by the topical ophthalmic route will not ordinarily cause acute problems. In case of overdosage, immediately flush eyes with water or normal saline. If accidentally ingested, drink fluids to dilute.

DOSAGE AND ADMINISTRATION

1 to 2 drops instilled into the conjunctival sac two to four times daily. During the initial 24 to 48 hours the dosage may be safely increased to 2 drops every hour. The physician may choose the dosage which affords optimal therapeutic effect in each case.

In order to minimise systemic absorption of PREDNEFRIN[®] FORTE eye drops, apply pressure to the tear duct immediately following administration of the drug.

Care should be taken not to discontinue therapy prematurely.

PRESENTATION

Eye drops, 10 mg/mL (1%): 10 mL (dropper bottle).

Storage: Store below 25°C. Protect from freezing.

Shelf life: 3 years.

Shake well before using.

To avoid contamination of the suspension, keep container tightly closed.

Do not touch dropper tip to any surface.

Discard contents 4 weeks after opening the bottle.

Contents are sterile if seal is intact.

Store upright.

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