

Acicot®

Eye & Ear Drops

PRESENTATION

Acicot® Eye & Ear drops is a clear colourless isotonic ophthalmic solution of Dexamethasone that is sterile until the bottle is opened. Each ml **Acicot®** Eye & Ear Drops contains Dexamethasone Phosphate 1mg (as Dexamethasone Sodium Phosphate BP).

DESCRIPTION

Dexamethasone is a glucocorticosteroid which suppresses the inflammatory response to a variety of agents. The antiphlogistic action of Dexamethasone is about 25 times that of hydrocortisone. Like all antiphlogistic glucocorticosteroids, Dexamethasone also inhibits phospholipase A₂, the first step in prostaglandin synthesis. Dexamethasone also inhibits the chemotactic migration of neutrophil cells to the focus of inflammation. There are at present no data on the possible systemic absorption of Dexamethasone after local application to the eye.

USES

Acicot® is indicated in the treatment of the following conditions.

Ophthalmic: **Acicot®** is indicated in the non-infectious forms of conjunctivitis, keratitis and blepharitis, especially of allergic origin, inflammation of the anterior uvea (iritis, iridocyclitis), scleritis, episcleritis and orbital myositis. **Acicot®** is also indicated for the treatment of corneal injury from chemical, radiation or thermal burns or following penetration by foreign bodies. Indicated for post operative use to reduce inflammatory reactions and suppress graft reaction.

Otic: Indicated in the steroid responsive inflammatory conditions of the external auditory meatus, such as allergic otitis externa, selected purulent and non-purulent infective otitis externa, when the hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

DOSAGE AND ADMINISTRATION

Eye: Instill one or two drops of solution into the conjunctival sac every hour during the day and every two hours during the night as initial therapy. When a favourable response is observed, reduce dosage to one drop every four hours. Later, further reduction to one drop three or four times daily may suffice to control symptoms.

Ear: Clean the aural canal thoroughly and sponge to dry. Initially instill three or four drops two or three times a day. When a favourable response is obtained, reduce dosage gradually and eventually discontinue.

However, the duration of treatment in both cases, will vary with the type of lesions and may extend from a few days to several weeks, according to therapeutic response.

CONTRA-INDICATIONS, WARNINGS, etc.

Contra-indications

- Hypersensitivity to ingredients.
- Herpes simplex and other virus conditions, mycosis.
- Glaucoma.
- Should not be used in new born.

Precautions: When no improvement is observed after 7-8 days treatment, other therapeutic measures should be considered. Dexamethasone may mask or exacerbate eye infections. During treatment with **Acicot®** the intraocular pressure should be measured regularly. Patients wearing contact lenses must not use the eyedrops during the time the lenses are worn.

Pregnancy : Controlled studies have not been performed with pregnant women. **Acicot®** ophthalmic solution should be used only if the potential benefit to the mother justifies the potential risk to the embryo or foetus.

Nursing mother: Because of the adverse reactions in nursing infants, the use to nursing mother depends on the importance of the drug to the mothers.

Paediatric use: Safety and effectiveness in children have not been established.

SIDE EFFECTS

A slight burning sensation may occur for a short time after instilling the drops into the eye. After several weeks administration to predisposed patients there may be reversible increase in intraocular pressure. Systemic adverse reactions may also occur after long term topical application of corticosteroids. Cataract and corneal softening have been reported after long term use of Dexamethasone in isolated cases.

DRUG INTERACTIONS

Using topical applications, the known interactions of corticosteroids are of secondary importance.

OVERDOSAGE

Topical long term intensive use may lead to systemic effects. Oral ingestion of the contents of one bottle (up to 10 ml) is unlikely to lead to any serious adverse effect.

DIRECTIONS FOR USE

The following steps should be considered to assure the right use **Acicot®**

- a. Proper administration technique for applying the solution to the eye and ear.
- b. Compliance with full course of therapy.
- c. Missed dose: Applying as soon as possible; not applying if almost time for next dose.
- d. Close bottle immediately after use.
- e. Proper storage of the medicament

Do not use longer than one month after opening. It is advisable to destroy any remaining medicament after completing treatment.

PHARMACEUTICAL PRECAUTIONS

Store in a cool place. Protect from freezing.

PACKAGE QUANTITIES

Acicot® Dropper bottle of 5 ml.

®Registered Trade Mark



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