

**TRADE NAME DICINAL PRODUCT**

[ Dexamethasone-21-dihydrogen phosphate, disodium salt 0.0985% eye gel (217) ]

**QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 g eye gel contains 0.985 mg of dexamethasone -21- dihydrogen phosphate, disodium salt.

**PHARMACEUTICAL FORM**

Eye gel

**CLINICAL PARTICULARS****1- Therapeutic Indications**

Non-bacterial inflammation of the cornea and conjunctiva without epithelial defect as well as inflammations in the interior part of the eyeball (iritis, iridocyclitis, uveitis).

As supplementary treatment to an antibiotic basic therapy in the presence of bacterial conjunctivitis and allergic conjunctivitis without epithelial defect.

**2- Dosage and method of administration**

- Initially, instill 1-2 drops every 4 hours into the lower conjunctival sac.

- When response initiates instill 1 drop every four hours.

- Later instill 1 drop 4 times a day.

*The duration of treatment should not exceed 4 weeks*

**3-Contra-indications**

Herpes superfacialis, bacterial and viral eye infections without concomitant anti-infective basic therapy, ocular tuberculosis, ophthalmic mycosis, ulcerous lesions of the cornea, narrow-and open-angle glaucoma, hypersensitivity to any ingredient of the medicinal product beside fungal eye infection.

**4-Warnings and Precautions**

Like all other corticoids, dexamethasone may impair the antibacterial resistance owing protein-catabolic effect and, thus, may occasionally also promote an infection. If an infection occurs, treatment with *Dexagel* should be discontinued until the infection has safely healed up under specific treatment, unless the inflammatory reaction is so severe that antiphlogistic treatment is absolutely necessary.

**5-Drug- Drug Interactions**

Special interactions with other medicinal products have not been reported. Nevertheless, there must be an interval of at least 5 minutes between applying *Dexagel* and other medications where *Dexagel* is the last to be instilled.

**6-Pregnancy and lactation<sup>®</sup>**

Since medical knowledge with regard to the topical administration of dexamethasone during pregnancy in humans is insufficient, *Dexagel* should not be used during this period, unless, in the judgment of a physician.

**7-Effects on ability to Drive and Use Machines**

Patients should exercise caution when driving vehicles or operating machinery. Even when used as indicated, this medicinal product may cause transient blurring of vision through formation of streaks.

**8-Undesirable Effects**

Under long-term treatment, glaucoma and cataract may develop in rare cases.

Diabetic may experience a rise in blood glucose level.

Allergic reactions may occur in isolated cases.

Secondary ocular infection from pathogens including herpes simplex, perforation of the globe.

*Note: Owing to the side effects mentioned above which may possibly occur with all corticosteroids, patients should be examined adequately by their ophthalmologist.*

**9- Overdose**

Overdosing due to frequent instillation increases the risk of side effects such as elevated intra-ocular pressure and the development of opacities of the lens.

**10- Precautions**

Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling the ophthalmic solution.