SUMMARY OF PRODUCT CHARACTERISTICS

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DEXACHLOR
EYE DROPS SOL 0.1 %+0.5 %

1. NAME OF THE MEDICINAL PRODUCT

DEXACHLOR

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each one (1) ml contains: Dexamethasone Sodium Phosphate 1.00 mg (0.1%) and Chloramphenicol 5.00 mg (0.5%).
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For inflammatory eye conditions that respond to corticosteroids and in cases of microbial contamination or risk of microbial contamination.
The ophthalmic corticosteroids are indicated in the following conditions:
Symptomatic treatment of allergic conditions of the conjunctiva, the cornea and the eyelid, regardless of the causal allergen.
Inflammatory conditions of the sclera and episclera, as well as the cornea. They are also administered postoperative mainly for intraocular surgery, eye-ball injuries and corneoplastic surgery.
It can be administered in infections from adenoviruses and common bacteria (conjunctivitis) in the early, intense phases of the inflammation, but under a general chemotherapy treatment.
In general, it is advisable to be avoided in all infectious conditions of the eye.

4.2 Posology and method of administration

One drop 3-4 times per day.

4.3 Contraindications

Hypersensitivity to any of the components.
In case of damage and ulceration of the cornea, especially if these are due to a virus such as herpetic epithelial keratitis, keratitis after vaccinia, trachoma, fungal infections, purulent inflammations without chemotherapeutic coverage of the corneal and eyelid, corneal ulcer and abscess. In case of tuberculous infections, glaucoma.
Long-term administration to children is also contraindicated, because as the corticoids are absorbed, they affect the pituitary-adrenal gland axis, rarely representing CUSHING syndrome signs.
In case of severe hematological disorders due to bone marrow failure. History of bone marrow failure. Hepatic dysfunction.
The use of chloramphenicol is contraindicated in neonates.

4.4 Special warnings and precautions for use

This pharmaceutical product contains thiomersal as a preservative, which is likely to cause allergic reactions.
Patients wearing contact lenses should remove them prior to instillation.
If there is no improvement after 7-8 days of use, other treatments must be considered. The same applies in case of allergic reaction. Chloramphenicol should not be used for a period exceeding 10 days. Generally it should be noted that corticosteroid treatment may cover, trigger or exacerbate an inflammation and that a change of treatment should be recommended in cases where no beneficial effects appear.
Furthermore, intraocular pressure should be checked due to risk of increasing (glaucoma).
The use of chloramphenicol is related to the potential risk of aplastic anemia and other blood dyscrasias.
The product should be used only when alternative therapies are ineffective and / or contraindicated.
Prolonged or frequent intermittent local use of chloramphenicol must be avoided because of the possibility of hypersensitivity reactions, including bone marrow hypoplasia which may lead to bone marrow aplasia.
Prolonged use of antibiotics may lead, in certain cases, to overdevelopment of resistant organisms, including fungi. If a contamination appears during treatment, use of the drug must be discontinued and appropriate actions should be taken. In non-superficial infections, local use of chloramphenicol should be followed by the appropriate, systematic administration of an antibiotic.
Use of chloramphenicol in childhood should be avoided.
Discontinuation of the drug after long-term use should be done gradually, as in the systematic administration of corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

DEXACHLOR Eye drops should not be used in combination with bactericidal ingredients which may impede the action of bacteriostatic antibiotics (penicillins, cephalosporins, gentamycin, tetracyclines, polymyxin-b, vancomycin sulfadiazine) or during systemic treatment with drugs which influence hematopoiesis, sulphonylureas, coumarin derivatives, hydantoins, methotrexate or as a preventive measure.
Reported interactions mainly concern systemic administration but should also be considered in the case of topical ophthalmic use.
The amount of dexamethasone contained in the product may increase the activity of barbiturates and tricyclic antidepressants
Salicylates may increase the effect of corticosteroids and antihistamines, barbiturates, phenylbutazone and rifampicin may increase the metabolism and thus reduce their effectiveness.

4.6 Pregnancy and lactation

Studies in animals have shown that chloramphenicol causes adverse effects on the fetus. It should not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Driving and operating machinery should be avoided during application of DEXACHLOR in the eye.

4.8 Undesirable effects

1. Hypertonia (cortisone glaucoma) after local use for over than two weeks
2. Blurring of the lens (cortisone cataract), following long-term administration.

3. Activation, deterioration or predisposition to infections from herpes simplex, fungi and bacteria (mainly pseudomonas).
4. Long-term administration to children or systemic absorption can cause blood disorders (chloramphenicol) or affection of the pituitary-adrenal axis representing CUSHING syndrome signs.
5. It is possible to observe delay in the healing of the corneal epithelium or of postoperative scars or in case of long-term treatment, corneal thinning, mydriasis and blepharoptosis.
6. In predisposed patients intraocular pressure may increase after a few weeks use. It is necessary to systematically measure the intraocular pressure.
7. This pharmaceutical product contains thiomersal (an organomercurial compound) as a preservative which may cause hypersensitivity reactions.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorization 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.

4.9 Overdose
There are no data concerning topical administration. In case of accidental ingestion, measures should be taken in order to reduce the absorption.

5. PHARMACOLOGICAL PROPERTIES

ATC Code S01CA01

5.1 Pharmacodynamic properties
DEXACHLOR contains a combination of an antimicrobial and a corticosteroid.
Chloramphenicol is a low molecular weight, lipophilic broad spectrum antimicrobial. It is effective against Gram + and Gram- bacteria, as well as the spirochete, Salmonella, the rickettsia and chlamydia (trachoma).
It has been demonstrated that the mechanism of action is the selective inhibition of bacterial protein synthesis. Chloramphenicol is moderately effective against proteus (20-30% strength), serratia (30-70%), klempsiela (60-70%), enterobacter (20-50%) and E. coli (20%). It is ineffective against pseudomonas, fungi and protozoa. Sensitization is rare. It passes through the cornea leading to achieve therapeutic levels in the anterior chamber.
Dexamethasone is a corticosteroid with anti-inflammatory activity which is about 25 times more potent than hydrocortisone. Like all anti-inflammatory corticosteroids it inhibits phospholipase A2, which the first step in the synthesis of prostaglandins. It also inhibits the chemotaxis of neutrophils at the site of inflammation.

5.2 Pharmacokinetic properties
Maximum concentration of 15μg / g in the cornea and 1 μg / g in the aqueous humor in rabbit eyes was measured after single administration of 50ml of a 0.15% Dexamethasone phosphate solution labeled with 14C. Chloramphenicol rapidly penetrates the cornea and is therapeutically active concentrations can be detected in the aqueous humor 15-30 minutes after topical administration; half-life is 3-5 hours, which is expected to be shorter in the inflamed eye.

5.3 Preclinical safety data
There are no other data in addition to those mentioned herein.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 400, Boric acid, Trometamol, α-Tocopheryl Acetate, Hypromellose, Thiomersal, Water for Injections.

6.2 Incompatibilities

There are no relevant studies.

6.3 Shelf life

Shelf-life of the closed bottle is 24 months.
Shelf-life of the bottle after first-opening is 28 days.

6.4 Special precautions for storage

Store in a refrigerator before the first opening (2°C - 8°C).
After the first opening, store at temperature below 30°C, protected from light and do not use this bottle for more than 28 days.

6.5 Nature and contents of container

White 10 ml LDPE bottle, white LDPE dropper, white HDPE-LDPE screw cap.

6.6 Special precautions for disposal and other handling

Shake the bottle well before use. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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