Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Phenidex Eye Drops

2. Qualitative and quantitative composition

Chloramphenicol 0.5%
Dexamethasone sodium phosphate 0.1%

Excipients with known effect
Borax and Boric acid (one ml of solution contains 3.075 mg boron)
Benzalkonium chloride

Refer to section 6.1 for full list of excipients

3. Pharmaceutical form

Eye drops.

4. Clinical particulars

4.1 Therapeutic indications

Acute and chronic keratitis and conjunctivitis of an infectious, allergic but non-viral nature. Infections of the anterior uvea (iritis, iridocyclitis). Scleritis, episcleritis and myositis, sympathetic ophthalmia. Postoperative management of cataract, glaucoma and strabismus. Chloramphenicol is indicated if the infective agent is resistant to other antibiotics.

4.2 Posology and method of administration

Dosage schedule:
Adult:
Insert one drop into the conjunctival sac 3-5 times per day for up to 10 days.

In acute cases: up to 1 drop every hour.

Paediatric:
Infants aged from 28 days to 3 months and Children aged less than 2 years should only be indicated in exceptional cases.

Should not be administered to infants aged less than 28 days.

4.3 Contraindications

- Hypersensitivity to the dexamethasone, chloramphenicol o to any of the excipients listed in section 6.1.
- Injuries and ulcerous processes of the cornea.

- Herpes simplex and other virus conditions.
- Mycoses and other fungal infections;
- Severe blood disorders due to bone marrow depression and hepatic dysfunctions.
- Newborn babies.
- Family history of bone marrow depression.

4.4 Special warnings and precautions for use

Corticosteroids could mask, activate or aggravate an infection in the eye. As with all corticosteroids, the dosage for babies and infants under 2 years of age should be selected with caution.

Chloramphenicol should not be used for more than 10 days. If no improvement is seen after 5 days of treatment, other therapeutic measures should be considered.

In very rare cases occurrence of bone marrow associated with long-term use of chloramphenicol, including topical ocular administration cannot be excluded. Irreversible form of aplasia might occur after a latent period of weeks and months.

Chloramphenicol therapy is associated with potential risk of aplastic anaemia or other hematodyscrasia.

Prolonged use of corticosteroids intended for ocular use may increase intraocular pressure glaucoma.

Monitoring is recommended for symptoms of superinfections caused by non-susceptible organisms, including fungi. In the event of superinfection, appropriate alternative treatment should be applied.

Ocular administration of corticosteroids immediately after cataract removal surgery may result in a delayed healing and increased incidence of bullae formation.

Patients wearing contact lenses should take the medication when the lenses are not worn.

A careful risk/benefit evaluation should therefore be made in each individual case. The product should only be used where alternative therapies are ineffective and/or contraindicated.

4.5 Interaction with other medicinal products and other forms of interaction

Phenidex should not be used concomitantly with bactericidal substances which may inhibit bacteriostatic antibiotics (penicillins, cephalosporins, gentamicin, tetracyclines, polymyxin B, vancomycin, sulphadiazine), nor

during concomitant systemic therapy with medicaments that impair haematopoiesis, sulphonylureas, coumarin derivatives, hydantoin or methotrexate (precautionary measure).

Concomitant use of topical corticosteroids and NSAIDs intended for ocular use in patients with a history of corneal inflammation is not recommended and caution is required.

In patients treated concomitantly with multiple products intended for topical ocular administration, it is necessary to provide an interval of not less than 5 minutes between the applications in order to avoid possible interactions.

4.6 Pregnancy and Lactation

Animal experiment with chloramphenicol have shown adverse effects on the foetus. However, no controlled human studies are available. Phenidex should not be prescribed to pregnant patients, to newborn infants, nor during lactation.

4.7 Effects on ability to drive and use machines

A slight sense of burning may occur for a short time after instillation of the product into the eye, without affecting the success of the treatment. Patients should be warned not to drive or operate hazardous machinery unless their vision is clear.

4.8 Undesirable effects

- The most commonly reported reactions are pruritus, conjunctival hyperemia, redness, oedema, foreign body sensation or other signs of irritation that were absent prior to treatment.

- The patient may notice a bitter taste shortly after instillation.

- When used for several weeks, a reversible increase in eye pressure is possible in predisposed patients. Regular pressure checks are advisable.

- Partially irreversible hemato-dyscrasia (aplastic anaemia, pancytopenia, leukopenia, thrombocytopenia, agranulocytosis) has been observed in isolated cases following topical use of chloramphenicol. However, the severity and the moment of manifestation of such partially irreversible and lethal effects did not correlate with the commonly elevated dosage used in these studies.

- Long term treatment with topical corticosteroids may cause adverse systemic effects (especially in children), rare cases of corneal softening and cataracts have been reported.

4.9 Overdose

Overdose through local administration is not known. In case of accidental oral intake, specific measures to reduce resorption should be taken. There is no specific antidote.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The inflammatory effect of dexamethasone is approximately 25 times stronger than that of hydrocortisone. As any anti-inflammatory glucocorticoid, one of the actions of dexamethasone is to inhibit the phospholipase A2 (PLA2), the first step in prostaglandin synthesis. Also, dexamethasone inhibits the chemotactic infiltration of neutrophiles into the site of inflammation.

Chloramphenicol is a low molecular weight, predominantly lipophilic, antibiotic, and is effective against Gram-positive and Gram-negative bacteria, and also against Spirochaetae, Salmonellas, Rickettsia and Chlamydiae (trachoma). The mechanism of action has been shown to be by selective inhibition of bacterial protein synthesis. Chloramphenicol is moderately effective against Proteus (20 50% resistance), Serratia (30-70%), Klebsiella (60-70%), Enterobacter (20-50%), and E. coli (20%). Chloramphenicol is ineffective against Pseudomonas, fungi and Protozoa. The resistance situation has not changed significantly in recent years.

5.2 Pharmacokinetic properties

A maximum concentration of 15 mcg/g in the cornea and 1 mcg/g in the aqueous humour of a rabbit's eye was measured after a single administration of 50 µL of a 0.1% 14C-labelled dexamethasone phosphate solution. Chloramphenicol penetrates readily into the cornea and therapeutically effective concentrations in the range of 3-6 mcg/mL can readily be detected in the aqueous humour 15-30 minutes after local administration. The half-life is 3-5 hours. In the inflamed eye, the retention time is expected to be substantially shorter.

5.3 Preclinical safety data

Not-Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

Boric acid
Borax10H2O
Sodium edetate
Polyoxy-40 stearate
Polyethylene glycol 400
Benzalkonium chloride
Highly purified water

6.2 Incompatibilities

Not Known.

6.3 Shelf-Life

24 months from manufacture.
28 days after opening the bottle.

6.4 Special Precautions for storage

Store between 2-8°C
Discard content 4 weeks after opening

7.1 Nature and Content of container

A flexible polypropylene bottle incorporating a polyethylene plug and cap assembly. The bottle contains 10 ml.

7.2 Special precautions for disposal and other handling

No special instructions.

8. Marketing Authorization Holder

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9. Marketing Authorization Number

CTD6382

10. Date of first authorization/renewal of the authorization

Date of the first authorization: 20/7/1994
Date of last renewal of authorization: 14/02/2025

11. Date of revision of the text

08/05/2025