SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Phenidex Eye Drops

2. Qualitative and quantitative composition

Chloramphenico 0.5%

Dexamethasone sodium phosphate 0.1%

Refer to section 6.1 for full list of excipients

3. Pharmaceutical form

Eye drops.

4.0 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.

4.3 Contraindications

- Hypersensitivity to the ingredients.
- Injuries and ulcerous processes of the cornea.
- Herpes simplex and other virus conditions; mycoses; Glaucoma.
- 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 7-8 days of treatment, other therapeutic measures should be considered. Chloramphenicol therapy is associated with potential risk of aplastic anaemia or other hematodyscrasia. 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.

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

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).

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 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after Authorisation 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 Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

-

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.

5.0 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

6.0 Pharmaceutical particulars

6**.1 List of excipients**

Boric acid

Borax10H_2O

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.

6.4 Special precautions for storage

- Store between 2-8°C

-Discard content 4 weeks after opening

6.5 Nature and contents of container

A flexible polypropylene bottle in corporating a polyethylene plug and cap assembly. The bottles contain 10 ml.

6.6 Special precautions for disposal and other handling

No special instructions.

7. Marketing authorization Holder

Amman Pharmaceutical Industries.
King Abdullah II Industrial State – Sahab – Amman

8. Marketing Authorization number:

H2025/CTD6382/12497

9. Date of first authorization/renewal of the authorization

17/02/2025

10. Date of revision of the text

22/08/2026