SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Framydex Eye/Ear Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Framycetin (as sulphate) 5mg

Dexamethasone Phosphate as sodium phosphate.....0.5mg

Gramicidin.....0.05mg

3. PHARMACEUTICAL FORM

Ear/Eye Drops, Solution
Clear colorless to light pale yellow aqueous ophthalmic solution.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

In the Eye: For the short-term treatment of steroid responsive conditions of the eye when prophylactic antibiotic treatment is also required, after excluding the presence of fungal and viral disease.

In the Ear: Otitis Externa.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults (and the Elderly) and Children:

In the Eye: One or two drops applied to each affected eye up to six times daily or more frequently if required.

In the Ear: Two or three drops instilled into the ear three or four times daily.

Method of administration

Auricular and Ocular use.

Treatment duration should be short (not to exceed 7 days).

4.3 CONTRAINDICATIONS

Viral, fungal, tuberculous or purulent conditions of the eye. Use is contraindicated if glaucoma is present or herpetic keratitis (e.g. dendritic ulcer) is considered a possibility. Use of topical steroids in the latter condition can lead to extension of the ulcer and marked visual deterioration.

Framydex Eye Drops is contraindicated in case of eardrum perforation because of the risk of ototoxicity.

Hypersensitivity to the active substances or to any of the excipients used in this product.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Topical corticosteroids should never be given for an undiagnosed red eye as inappropriate use is potentially blinding.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Treatment with corticosteroid/antibiotic combinations shuld not be continued for more than 7 days in the absence of any clinical improvement, since prolonged use may lead to occult extension of infections due to the masking effect of the steroid. Prolonged use may also lead to skin sensitisation and the emergence of resistant organisms.

Treatment with corticosteroid preparations should not be repeated or prolonged without regular review to exclude raised intraocular, pressure, cataract formation or unsuspected infections.

Aminoglycoside's antibiotics may cause irreversible, partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is dose related and is enhanced by renal or hepatic impairment. Although this effect has not been reported following ocular use, the possibility should be considered when high dose topical is given to small children or infants.

Paediatric Population

Prolonged use may lead to the risk of adrenal suppression in infants.

4.5 Interaction with other medical products and other forms of interaction

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side effects.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. There is a risk of foetal ototoxicity if aminoglycoside antibiotics preparations are administrated during pregnancy.

4.7 Effects on Ability to Drive and Use Machines

Framydexeye drops solution may cause transient blurring of vision on instillation. Patients must not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable Effects

The following CIOMS frequency rating is used: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10 000 to <1/1000); very rare (<1/10 000), not known (cannot be estimated from the available data).

Eye disorders

Not known: Blurred vision (see also section 4.4)

Hypersensitivity reactions, usually of the delayed type, may occur leading to irritation, burning, stinging, itching and dermatitis.

Topical steroid use may result in increased intraocular pressure leading to optic nerve damage, reduced visual acuity and visual field defects.

Intensive or prolonged use of topical corticosteroids may lead to formation of posterior subcapsular cataracts.

In those diseases causing thinning of the cornea or sclera, corticosteroid therapy may result in the thinning of the globe leading to perforation.

Reporting of suspected adverse reactions

Healthcare professionals are requested to report any suspected adverse reactions via national Pharmacovigilance Electronic Reporting Systems to the respective national regulatory authorities.

4.9 OVERDOSE

Long-term intensive topical use may lead to systemic effects.

Oral ingestion of the contents of one bottle (up to 10ml) is unlikely to lead to any serious adverse effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: ophthalmological and otological preparations, corticosteroids and antiiinfectives in combination, ATC Code: S03CA01.

Mechanism of action

Framycetin Sulphate is an aminoglycoside antibiotic with a spectrum of activity similar to that of neomycin, this includes *Staph. aureus* and most clinically significant gram-negative organisms.

Gramicidin is an antimicrobial cyclic polypeptide active in vitro against many gram-positive bacteria. It is used for the local treatment of susceptible infections, sometimes in combination with other antimicrobial agents and frequently with a corticosteroid.

Dexamethasone is a synthetic glucocorticoid and has the general properties as other corticosteroids.

5.2 PHARMACOKINETIC PROPERTIES

Framycetin Sulphate absorption occurs from inflamed skin and wounds. Once absorbed it is rapidly excreted by the kidneys in active form. It has been reported to have a half-life of 2-3 hours

Gramicidin has properties similar to those of Tyrothricin and is too toxic to be administered systemically.

Dexamethasone is readily absorbed from the gastro-intestinal tract. It has a biological half-life in plasma of about 190 minutes.

5.3 PRECLINICAL SAFETY DATA

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Not applicable

6.2 Shelf life

3 years.

6.3 Special precautions for storage

Store below 30°C.

Protect from light, heat and moisture.

Keep out of reach of children

6.4 Nature and content of container

1×5ml LDPE Bottle with insert in carton.

6.5 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

Helix Pharma (Pvt.) Limited

Hakimsons House

A/56, S.I.T.E., Manghopir Road

Karachi, Pakistan.

8. MARKETING AUTHORISATION NUMBER(S)

H2002/041/R1

9.DATE OF FIRST AUTHORIZATION/ RENEWAL OF AUTHORIZATION

2026 July 14

10. DATE OF REVISION OF THE TEXT

2026 July 14