1. NAME OF MEDICINAL PRODUCT

Pharmadexneocin eye/ear drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains
Dexamethasone (as dexamethasone phosphate) 0.1%$^{w}/_{v}$.
Neomycin sulphate 0.35%$^{w}/_{v}$.

For full list of Excipients, see section 6.1

3. PHARMACEUTICAL FORM OF THE DRUG PRODUCT

Eye/Ear Drop
10ml clear colourless to slightly yellow solution

4. CLINICAL PARTICULARS

4.1 INDICATIONS

Pharmadexneocin is used for the treatment of eye or ear inflammations when concurrent use of an anti-microbial is judged necessary.
It is indicated 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.

4.2 Posology and method of administration:

The normal dosage is one drop to be put in the affected eye 4 -6 times a day or as advised by your doctor.
Do not touch your eye with the dropper on the bottle as this may contaminate the drops

4.3 Contraindications:

Hypersensitivity to the active substances or to any component of the preparation: • Epithelial herpes simplex keratitis.

- Vaccinia, varicella, or other viral infection of cornea and conjunctiva (except herpes zoster keratitis).
- Fungal disease s of ocular structures.
- Mycobacterial ocular infections.

4.4 Special warnings and pre cautions for use For ocular use only. Not for injection or ingestion.

As with all antibacterial preparation prolonged use may lead to overgrowth of non-susceptible bacterial strains or fungi. If superinfection occurs, appropriate therapy should be initiated.
Sensitivity to topically applied aminoglycosides may occur in some patients. Cross-sensitivity to other aminoglycosides may also occur. If signs of serious reactions or hypersensitivity occur, discontinue the use of this product. Patients using ophthalmic preparations containing neomycin sulphate should be advised to consult a physician if ocular pain, redness, swelling, or irritation worsens or persists.
Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic neomycin or when applied topically to open wounds or damaged skin.
Prolonged use of ophthalmic steroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, reduced visual acuity and visual field defects, and posterior subcapsular cataract formation. In patients receiving prolonged ophthalmic corticosteroid therapy, intraocular pressure should be checked routinely and frequently.
In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids.

4.5 Interactions with other medicinal products and other forms of interactions

No interaction studies have been performed.
Concomitant and/or sequential use of an aminoglycoside (neomycin) and other systemic, oral, or topical drugs that have neurotoxic, ototoxic, or nephrotoxic effects may result in additive toxicity and should be avoided, whenever possible. If more than one ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart.

4.6 Pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Pharmadexneocin eye/ear drops in pregnant women. Studies in animals with some active components of Pharmadexneocin eye/ear drops have shown reproductive toxicity. Pharmadexneocin eye/ear drops, suspension is not recommended during pregnancy.

Lactation

It is unknown whether topical ophthalmic dexamethasone and neomycin are excreted in human milk. Because systemic corticosteroids and aminoglycosides may be distributed into milk, a risk to the suckling child

cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue therapy with Pharmadexneocin eye/ear drops taking into account the benefit of breast-feeding for the child and the benefit of the product to the mother.

4.7 Effects on ability to drive and use machines

Pregnancy

There are no or limited amount of data from the use of Pharmadexneocin eye/ear drops in pregnant women. Studies in animals with some active components of Pharmadexneocin eye/ear drops have shown reproductive toxicity.

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Lactation

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A decision must be made whether to discontinue breast-feeding or to discontinue therapy with Pharmadexneocin eye/ear drops taking into account the benefit of breast-feeding for the child and the benefit of the product to the mother.

4.8 Undesirable effects

Due to the steroid component, in diseases causing thinning of the cornea or sclera there is a higher risk for perforation especially after long treatments.Topical ophthalmic steroid use may result in increased intraocular pressure with damage to the optic nerve, reduced visual acuity and visual field defects. Also it may lead to posterior subcapsular cataract formation.

Sensitivity to topically administered aminoglycosides may occur in some patients. Systemic side effects may occur with extensive use.

4.9 Overdose

No case of overdose has been reported. Signs and symptoms of an overdosage of Pharmadexneocin eye/ear drops may be similar to adverse reaction effects seen in some patients (punctuate keratitis, erythema,

increased lacrimation, oedema and lid itching).A topical ophthalmic overdose of Pharmadexneocin eye/ear drops may be flushed from the eye(s) with lukewarm water.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of Action

Pharmadexneocin eye/ear drops have a dual effect: suppression of inflammation symptoms by the corticosteroidal component dexamethasone, and an antiinfective effect due to the presence of antibiotic neomycin.

Dexamethasone is a synthetic glucorticoid with potent anti-inflammatory activity. Neomycin is an aminoglycoside antibiotic that primarily exerts its effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome.

Mechanism of Resistance

Resistance to neomycin occurs by several different mechanisms including (1) alterations of the ribosomal subunit within the bacterial cell; (2) interference with the transport of neomycin into the cell, and (3) inactivation by an array of adenylating, phosphorylating, and acetylating enzymes. Genetic information for production of inactivating enzymes may be carried on the bacterial chromosome or on plasmids.

Dexamethasone is a moderately powerful corticosteroid having good penetration in ocular tissue. Corticosteroids have an anti-inflammatory as well as a vasoconstrictive effect. They suppress the inflammatory response and symptoms in various disorders without basically curing these disorders.

5.2 Pharmacokinetic properties

Dexamethasone, like other corticosteroids, is absorbed rapidly after oral administration and has a biological half-life of about 190 minutes. Sufficient absorption may occur after topical application to the skin and eye to produce systemic effects. Intraocular penetration of dexamethasone occurs in significant amounts and contributes to the effectiveness of dexamethasone in anterior segment inflammatory disease.

Neomycin is poorly absorbed from the gastrointestinal tract and after topical administration an insufficient amount is absorbed to produce systemic effects. Absorption has been reported to occur from wounds and

inflamed skin. After absorption neomycin is rapidly excreted by the kidneys in active form.

5.3 Preclinical safety data

Mutagenicity and Carcinogenicity

Genotoxicity studies performed with neomycin with and without metabolic activation, were negative in bacterial (Ames test) or mammalian cells (chromosomal aberration assay in CHO cells).
Dexamethasone was clastogenic in vivo in the mouse micronucleus assay at doses in excess of those obtained following topical application.

Teratogenicity

Dexamethasone has been found to be teratogenic in animal models. Dexamethasone induced abnormalities of foetal development including cleft palate, intra-uterine growth retardation and effects on brain growth and development.

Local Tolerance and Systemic Effects

Systemic exposure to dexamethasone is associated with its pharmacological effects as a potent glucocorticoid. Prolonged exposure to the steroid can result in glucocorticoid imbalance. Topical ocular safety studies with dexamethasone in rabbits have shown systemic effects after 1 month of treatment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Sodium metabisulphite
Benzalkonium chloride
Sodium phosphate dibasic
Sodium phosphate monobasic
Creatinine
Water for injection

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened shelf-life is 24 months.
Opened shelf-life 28 days.
But the patient is advised to discard any remaining drops after the prescribed course of treatment.

6.4 Special precautions for storage

Store in a cool place (Below 30° C) away from light. Keep out of reach of children

6.5 Nature and contents of container

10ml low density polyethylene bottles with a polypropylene spiked cap.

6.6 Special precautions for disposal

No special requirement

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

FDA/SD.223-050597

9. DATE OF FIRST REGISTRATION/ RENEWAL OF REGISTRATION

11/05/2022

10. DATE OF REVISION OF TEXT

18/08/2025