SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

NETRACORTIL (Oxytetracycline Hydrochloride, Hydrocortisone Acetate and Polymyxin B Sulphate Eye/Ear Suspension)

2. Qualitative and quantitative composition

Each ml contain:

Oxytetracycline Hydrochloride USP

Eq.to Oxytetracycline……10mg

Hydrocortisone Acetate USP ……5mg

Polymyxin B sulfate USP …….10000IU

In a Maineral oil suspension…….....q.s.

3. Pharmaceutical form

Eye/Ear suspension for ophthalmic and otic use only

4. Clinical particulars

4.1 Therapeutic indications

Netracortil Eye/Ear applications are indicated in the topical treatment of corticosteroidresponsive inflammatory conditions of the eye and ear in which infection due to organisms susceptible to oxytetracycline Hydrochloride, Hydrocortisone Acetate and polymyxin B sulfate exist.

4.2 Posology and method of administration

Eye: Instil one to two drops into the affected eye three times daily.

Ear:Instil two to four drops into the affected ear three times daily.

Eye: Instil a small quantity (approximately 1 cm) of the ointment into the affected eye two or three times daily.

Ear:Instil a small quantity (approximately 1 cm) into the affected ear three or four times daily.

4.3 Contraindications

Acute herpes simplex, vaccinia, varicella and other viral diseases of the cornea and conjunctiva, viral otic infections

2. Tuberculosis, Mycobacterial infection of the eye.

3. Fungal diseases of ocular and auricular structures.

4. Acute purulent infections (may be masked or enhanced by the presence of the steroid.)

5. Hypersensitivity to any of the components of the medicines.

6. Mechanical lacerations and abrasions of the eye.

7. Perforation of the eardrum.

8. Opthalmic use of these combinations is always contraindicated after uncomplicated removal of a corneal foreign body.

4.4 Special warnings and precautions for use

Corneal ulceration may be aggravated by the presence of the steroid. It is important that corneal ulcers are correctly diagnosed before treatment with Netracortil (oxytetracycline Hydrochloride,Hydrocortisone Acetate and polymyxin B sulfate) is initiated. Prolonged use of ophthalmic cortiocosteroids may result in glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. A steroid-glaucoma may be induced after a week or more of treatment in patients predisposed to chronic simple glaucoma. Furthermore, topical corticosteroid therapy frequently induces intraocular hypertension in normal eyes and increases pressure in eyes with initially elevated pressure. Intraocular pressure should be monitored frequently during therapy. In those diseases causing thinning of the cornea, perforation has been shown to have occurred with the use of topical steroids. In acute purulent conditions, steroids may mask infection or enhance existing infection. Local application of corticosteroids to the eyes of patients with bacterial, viral and fungal conjunctivitis may mask evidence of progression of infection until sight is lost. Corticosteroids may cause progression of dendritic keratitis (herpes simplex infection)

resulting in irreversible clouding of the cornea. Prolonged use may supress the host response and thus increase the hazard of secondary ocular infections. As with other antibiotic preparations, Netracortil (oxytetracycline Hydrochloride, Hydrocortisone Acetate and polymyxin B sulfate) may result in overgrowth of resistant organisms, particularly Candida and staphylococci. Constant observation of the patient is essential. If new infections of the cornea due to non-susceptible bacteria or fungi appear during therapy, appropriate measures should be taken. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled. If irritation develops the product should be discontinued and appropriate therapy instituted. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored. Employment of steroid medication in the treatment of herpes simplex requires great caution.The

possibility of persistent fungal infections of the cornea should be considered after prolonged steroid dosing. Supplemental therapy with oral oxytetracycline is advisable in the treatment of severe infections or those which may become systemic.

4.6 Pregnancy and lactation

The safety in pregnancy and lactation has not been established

USE IN CHILDREN

Systemic administration of tetracyclines during tooth development (last half of pregnancy, infancy, and childhood to the age of 8 years) may cause permanent discoloration of the teeth as well as retardation in the development of the skeleton. Enamel hypoplasia has also been reported. Although these effects are unlikely following topical application of tetracyclines because of the low doses used, the possibility that these effects could occur should be considered.

PRECAUTIONS

Allergic reactions due to individual hypersensitivity including contact dermatitis may occur but are rare. Reactions occurring most often from the presence of the oxytetracycline are allergic sensitizations. Increased Lacrimation, a transient stinging or burning sensation, and a foreign body sensation have been reported occasionally with opthalmic tetracycline products.

The reactions due to the steroid component in decreasing order of frequency are: elevation of intraocular pressure with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing. Should signs of local irritation occur, discontinue treatment immediately. Elevation of intraocular pressure - Warnings. Secondary infection: The development of secondary bacterial or fungal infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid. With long-term applications of steroids, the cornea is particularly prone to develop fungal infections. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used. Secondary bacterial ocular infection following suppression of host responses also occurs. The use of Netracortil (oxytetracycline Hydrochloride,Hydrocortisone Acetate and polymyxin B sulfate) Eye/Ear Suspension with Polymixin B and Netracortil (oxytetracycline and hydrocortisone) Eye/Ear ointment with Polymixin B should be discontinued if such reactions occur.

4.5 Interaction with other medicinal products and other forms of interaction

Not Available

4.6 Pregnancy and lactation

The safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

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Secondary infection: The development of secondary bacterial or fungal infection has occurred after use of combinations containing steroids and antimicrobials. Fungal infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroid. With long-term applications of steroids, the cornea is particularly prone to develop fungal infections. The possibility of fungal invasion must be considered in any persistent corneal ulceration where steroid treatment has been used. Secondary bacterial ocular infection following suppression of host responses also occurs. The use of Netracortil Eye/Ear Suspension with Polymixin B should be discontinued if such reactions occur.

4.9 Overdose

Signs and symptoms

Known symptoms of overdosage and particulars of its treatment

In the event of overdosage treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Oxytetracycline is a product of the metabolism of Streptomyces rimosus and is one of the family of tetracycline antibiotics. It is primarily bacteriostatic and is thought to exert its antimicrobial effect by the inhibition of protein synthesis. Oxytetracycline is effective against a wide range of gram-negative and gram-positive organisms. Polymyxin B Sulfate is one of a group of related antibiotics derived

from Bacillus polymyxa. It is rapidly bactericidal but exclusively against gram-negative organisms. It is particularly effective against Pseudomonas aeruginosa and Haemophilus aegyptius (Koch-Weeks bacillus) frequently found in local infections of the eye and ear. Hydrocortisone acetate is a corticosteroid with anti-inflammatory, anti-pruritic and vasoconstrictive actions.

Pharmaceutical Particulars

6.1 List of excipients

Aluminium stearate, Heavy liquid paraffin

6.2 Incompatibility

Not known

6.3 Shelf life

24 months

6.4 storage conditions

Store at a temperature not exceeding 30°C.Protect from light. Keep out of reach of children.

6.5 Presentation

5ml Netracortil Eye/Ear suspension packed in a Aluminium collapsible tube further packed in a unit carton

6.6 Special Precautions for Disposal and Other Handling

Not applicable

7. Marketing authorisation holder

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8. Marketing authorisation number(s)

05922/3043/NMR/2016

9. Date of first authorisation/renewal of the authorisation

May 12, 2021

10. Date of revision of the text

July 2023