Drugfield Pharmaceuticals Limited

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Oxycortril®-B Eye/Ear Suspension

1. NAME OF THE MEDICINAL PRODUCT

Oxycortril®-B Eye/Ear Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains Oxytetracycline HCl 10mg, Hydrocortisone 5mg, Polymixin B 10,000iu.

(For a full list of excipients, see section 6.1).

3. PHARMACEUTICAL FORM

Sterile- Eye Suspension

4. Clinical particulars

4.1 Therapeutic indications

Oxycortril- B® Eye/Ear Suspension is effective in the treatment of blepharitis of the eyelid, conjunctivitis of the conjunctiva, scleritis, epideritis of sclera. It is useful in non-specific inflammatory conditions involving the cornea, particularly where neo-vascularization is a problem. It is effective in infections of the external ear canal caused by organisms susceptible to oxytetracycline and Polymyxin- B especially where there is mixed bacterial etiology; Hydrocortisone is indicated in infections of undetermined etiology that are accompanied by inflammatory reactions.

4.2 Posology and method of administration

Ophthalmic: Allow one or two drops into the affected eye three times daily.
Otic: Allow 2-4 drops into the external ear canal for treatment of infections three times daily or as prescribed by the physician.

4.3 Contraindications

Oxycortril-B®- Eye and Ear Suspension is contraindicated in persons who have shown hypersensitivity to any of the components and also after uncomplicated removal of a cornea foreign body in eye. Otic use is not recommended when there is perforation of the ear drum.

4.4 Special warnings and precautions for use

Oxytetracycline just like other tetracyclines should not be used during pregnancy because of effects on the developing foetus. Use during breast-feeding and in children up to age 12 years may result in impaired bone growth and permanent discolouration of the child's teeth.

4.5 Interaction with other medicinal products and other forms of interaction

None Known

4.6 Pregnancy and Lactation

The product should not be used in pregnancy unless absolutely essential. Tetracyclines cross the placenta and may have toxic effects on foetal tissues, particularly on skeletal development. The use of tetracycline compounds during pregnancy has been associated with reports of maternal liver toxicity. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the foetus. Tetracyclines are also excreted in breast milk and are therefore contraindicated in nursing mothers.

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

Hydrocortisone and oxytetracycline are well tolerated by the epithelial tissues and may be used topically with minimal untoward effects. Allergic reactions, including contact dermatitis may occur occasionally, but are rare.

Reactions occurring most often from the presence of the anti-infective ingredients are allergic sensitisations.

The following local side effects have been reported with topical corticosteroids, especially under occlusive dressings; burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

Oxycortril-B® Eye/Ear suspension should be discontinued if such reactions occur.

4.9 Overdose

There is no specific antidote available. In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Oxytetracycline

Oxytetracycline is a broad spectrum tetracycline antibiotic with activity against a large number of gram positive and gram negative bacteria. The product acts by interfering with bacterial protein synthesis.

Hydrocortisone

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. It is used topically for its anti-inflammatory effects, mediated by the reduction of formation, release and action of the various vasoactive chemicals released during inflammation. Thus producing suppression of the clinical manifestations of the disease in a wide range of disorders where inflammation is a prominent feature.

5.2 Pharmacokinetic properties

Oxytetracycline

Oxytetracyclines are incompletely and irregularly absorbed from the gastrointestinal tract.

The degree of absorption is diminished by the soluble salts of divalent and trivalent metals, with which tetracyclines form stable complexes and to a variable degree by milk or food. Plasma concentrations will depend upon the degree of absorption. Peak plasma concentrations occur about 1 to 3 hours after ingestion.

It is recommended that tetracyclines should be given before food.

A dose of 500mg every 6 hours by mouth is reported to produce steady-state plasma concentrations of 3 to 4µg per ml.

In the circulation, tetracyclines are bound to plasma proteins in varying degrees, but reported values differ considerably: from about 20 to 40% for oxytetracycline.

They are widely distributed throughout the body tissues and fluids. Small amounts appear in saliva, and the fluids of the eye and lung.

Tetracyclines appear in the milk of nursing mothers where concentrations may be 60% or more of those in the plasma. They diffuse across the placenta and appear in the foetal circulation in concentrations of about 25 to 75% of those in the maternal blood. Tetracyclines are retained at sites of new bone formation and recent calcification and in developing teeth.

The tetracyclines are excreted in the urine and in the faeces. Renal clearance is by glomerular filtration.

The tetracyclines are excreted in the bile where concentrations 5 to 25 times those in plasma can occur. Since there is some enterohepatic reabsorption complete elimination is slow. Considerable quantities occur in the faeces after administration by mouth.

Hydrocortisone

Hydrocortisone Following topical steroid application, variable absorption has been reported especially when applied to large surfaces, under occlusive dressing or for prolonged periods of time.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

None.

6.3 Shelf life

48 Months

6.4 Special precautions for storage

Store below 30°C in tight container protected from light and moisture.

6.5 Nature and contents of container and special equipment for use, administration or implantation

Oxycortril-B® Eye/Ear suspension is presented in the tube containing 5ml suspension.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

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