

1. NAME OF THE MEDICINAL PRODUCT

PENICILLIN® OPHTHALMIC AND SKIN OINTMENT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml

1g of Ophthalmic Ointment Contains.....Benzyl Penicillin Potassium 5000 I.U

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Ointment

4. Clinical particulars

4.1 Therapeutic indications

Local treatment of acute topical infections of the eye conjunctivitis, gonorrheal conjunctivitis, blepharitis, keratitis, dacryocystitis, injury of conjunctiva, hordeolum and in prophylaxis prior to surgery on the eye. Local treatment of topical infections of the skin: furuncull, burns, ulcers, infected wounds, abscess, impetigo, intertrigo, secondary infected ezcema, as well as in the prevention of infections.

4.2 Posology and method of administration

Posology

Ophthalmic Ointment: Apply a sparing amount of the ointment to the inverted low eyelid every 6-8 hours.

Skin Ointment: apply in a thin layer to the affected area 2-3 times daily. Cover with a sterile dressing in order to avoid contamination of the affected area.

4.3 Contraindications

Hypersensitivity to Penicillin.

4.4 Special warnings and precautions for use

Before using Penicillin Eye Ointment, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed

on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- do not take by mouth. Consult with your doctor before using this medicine on open wounds, dry, chapped, irritated, or sun-burned skin.
- wash your hands before and after applying Penicillin Eye Ointment. Clean and dry the skin area to be treated.
- do not wash the treated area after immediately applying Penicillin Eye Ointment. Also avoid the use of other products on the treated area unless directed by your doctor.
- applying an excessive amount may result in pilling. Use a thinner layer or lesser quantity of medicine to avoid pilling.
- avoid getting this medication in your eyes or nose or mouth.

4.5 Interaction with other medicinal products and other forms of interaction

Not Applicable

4.6 Fertility, pregnancy and lactation

Penicillin belongs to FDA pregnancy category B. No severe adverse events are observed with penicillin.

Breastfeeding Women: According to literature, penicillin can be found in milk at low levels that are unexpected to cause adverse reactions in breastfed infants. It is sometimes reported that penicillin can disrupt the infant's gastrointestinal flora, causing diarrhea or thrush; however, these side effects have not been adequately evaluated. Penicillin is acceptable for nursing mothers.

4.7 Effects on ability to drive and use machines

Instillation of this eye ointment may cause transient blurring of vision. Warn patients not to drive or operate hazardous machinery until vision is clear.

Adverse Reactions

Exofoliate dermatitis (red scaly skin) skin rash, hives or itching.

4.8 Undesirable effects

Following systemic absorption, symptoms of penicillin in overdose include neuromuscular hypersensitivity (agitation, hallucination, asterixis, encephalopathy, confusion, seizures) and electrolyte imbalance, with potassium especially in renal failure.

4.9 Overdose

Antidote in the event of overdosage

Rinse the eye with large quantity of water and report to your ophthalmologist if symptoms persist. In the event of accidental ingestion treatment of penicillin overdose should be symptomatic and supportive. Patients in whom intentional overdose is known or suspected should be referred for psychiatric consultation.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals, anti-infectives, Beta lactam,

ATC code: S01AA14

It has a wide range of clinical indications. Penicillin is effective against many different infections involving gram-positive cocci, gram-positive rods (e.g., *Listeria*), most anaerobes, and gram-negative cocci (e.g., *Neisseria*).

5.2 Pharmacokinetic properties

Absorption

When given topically to the eye, Penicillin is absorbed into the aqueous humour, cornea, iris, choroid, ciliary body and retina. Systemic absorption occurs but may be significant only at higher dosages or in extended paediatric therapy. Approximately 60–73% of an oral dose of penicillin potassium is absorbed from GI tract in healthy, fasting adults. Considerable interindividual variation in extent of oral absorption; some patients may not absorb therapeutic concentrations of oral penicillins. Peak serum concentrations attained within 30–60 minutes.

Distribution

Widely distributed into body tissues. Highest concentrations in kidneys; also distributed into liver, skin, intestines, bile, tonsils, maxillary sinus secretions, saliva, and ascitic, synovial, pleural, and pericardial fluids. Only minimal amounts distributed into CSF. Crosses human placenta. Distributed into human milk. Plasma Protein Binding Approximately 75–89%.

Metabolism

Metabolized in the liver. Approximately 35–70% of an oral dose metabolized to penicilloic acid which is microbiologically inactive.

Elimination Route

Penicillin and metabolites principally excreted in urine by tubular secretion. Approximately 20–65% of an oral dose excreted in urine as unchanged drug and metabolites within 6–8 hours; small amounts excreted in feces and bile. Serum half-life is 0.5 hours in adults with normal renal function.

5.3 Preclinical safety data

The use of Penicillin eye ointment, and its derivatives, in ophthalmology is well established. Little relevant toxicology has been reported, however, the breadth of clinical experience confirms its suitability as a topical ophthalmic agent.

6. Pharmaceutical particulars

6.1 List of excipients

Penicillin Potassium (Sterile)
Liquid Paraffin Light
White Soft Paraffin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store below 30 °C. Protect from light and moisture.
Replace cap immediately after use.

6.5 Nature and contents of container

PENICILLIN® OPTHALMIC OINTMENT is available in tube containing 5g of Ophthalmic Ointment.

6.6 Special precautions for disposal and other handling

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

7.0 Applicant/Manufacturer

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