

OPCIN 0,3%



Eye drops, solution S01AA23

Netilmicin

Composition Multidose eye drops

100 ml contain: Active principle: Netilmicin sulphate g 0.455 equivalent to Netilmicin g 0.300 Excipients: Sodium chloride - Benzalkonium chloride - Purified water.

Pharmaceutical form and content

5 ml bottle eye drops, solution

Pharmacotherapeutic category

Netilmicin is an aminoglycoside antibiotic.

Marketing Authorisation Holder:

S.I.F.I. S.p.A. - Via Ercole Patti, 36 – Lavinaio – 95020 Aci S. Antonio –(Catania) - Italy

Manufacturer:

S.I.F.I. S.p.A. - Site located in Lavinaio - Aci S. Antonio (Catania) Italy

Therapeutic indications

Topical treatment of external infections of the eye and its adnexa caused by germs sensitive to Netilmicin, including those producing adenylating or phosphorylating enzymes.

Contraindications

Patient's hypersensitivity to the drug components or to any other aminoglycoside.

Precautions for use

Prolonged use of topical products may determine sensitisation phenomena.

In such cases discontinue treatment and consult the physician to start an adequate therapy. In infants and pregnant women the product should be administered in case of real need and under strict medical control. The use of the product is not recommended during lactation. OPCIN EYE DROPS is not injectable; therefore, it must not be injected subconjunctivally or introduced in the anterior chamber.

Pharmacological interactions

No significant pharmacological interactions have ever been reported further to the use of netilmicin as eye drops. Concomitant administration, even topical and especially intracavitary, of other potentially nephro- and ototoxic antibiotics may increase the risk of such effects.

An increase in potential nephrotoxicity of some aminoglycosides is reported further to subsequent or concomitant use - which should be avoided - of other potentially nephrotoxic drugs such as cisplatin, polymyxin B, colistin, viomycin, streptomycin, vancomycin, other aminoglycosides and some cephalosporins (cephaloridin) or potent diuretics such as ethacrynic acid and furosemide for their effects on kidneys.

In vitro, the association of an aminoglycoside with a beta-lactam antibiotic (penicillins or cephalosporins) may cause a reciprocal and relevant inactivation. A reduction of half-life or plasma levels of aminoglycoside occurred in patients suffering from renal insufficiency and in some patients with normal renal activity, even if an aminoglycoside and a penicillin-like antibiotic were administered by two different routes.

Special warnings

Prolonged use of topical antibiotics may determine overgrowth of resistant micro-organisms. Should no significant clinical improvement be reported within a relatively short period of time or should any irritation or sensitisation phenomena occur, it is necessary to discontinue treatment and start an adequate therapy.

Posology and method of administration

Instil 1 or 2 drops in the conjunctival sac 3 times daily, or according to medical prescription.

Possible side effects

OPCIN may occasionally cause slight and transient ocular irritation or sensitisation phenomena such as oedema, urticarial eruptions and pruritus.

Patients are kindly requested to inform their doctor or chemist of any side effect not described in this leaflet.

Expiry date

Expiry date is indicated on the outer package

Warning: the product shall not be used after the expiry date indicated on the package

Store below 25 °C

OPCIN 5 ml eye drops shall not be used after 28 days from first opening of the bottle.

OCULAR USE

KEEP OUT OF THE REACH OF CHILDREN

Directions for use:

Multidose eye drops



Close the bottle by screwing the spike top thoroughly. Screw the cap tight to pierce the bottle.



Unscrew the spike top, turn the bottle up-side-down and instil by gently squeezing of the bottle.



Close the bottle by screwing the spike top thoroughly.

