GENTAMICIN-POS® EYE OINTMENT
5.0 mg gentamicin sulfate (= 3.0 mg gentamicin)
Antibiotic ophthalmic drug

PRODUCT DESCRIPTION

Gentamicin-POS® eye ointment (5.0 mg/g gentamicin sulfate) is a yellowish, translucent suspension ointment filled in a 2.5 g aluminium tube.

PHARMACOLOGY

Pharmacodynamics

The aminoglycoside antibiotic gentamicin belongs to the antibiotic substances, which interfere both in the resting stage and in the proliferation stage of the sensititve germs with the protein synthesis on the ribosomes.
Gentamicin binds to the 30S-subunit of the bacteria ribosome, which leads to a misreading of the m-RNA.
The misreading and the resulting proteins with wrong amino acid sequences generate disorders of the membrane function in the bacteria, which lead to a discharge of cytoplasmic constituents. Furthermore, wrong, functionally inefficient enzyme- and structure-proteins result.

Pharmacokinetics

After topical application to the affected eye gentamicin is absorbed by cornea and conjunctiva. After 15 minutes gentamicin was found in the aqueous humor. Gentamicin, however, does not diffuse through the healthy cornea and measurements of the aqueous humor confirm that no effective antibacterial concentration of gentamicin can be achieved after application of eye ointment to the undamaged cornea.

INDICATIONS AND CLINICAL USE

Gentamicin-POS® is indicated in infections of the anterior eye including conjunctivitis, keratitis, blepharitis, and hordeolum, caused by gentamicin-sensitive pathogens. Gentamicin-POS® eye ointment is also used for post-operative antibacterial prophylaxis.

DOSAGE AND ADMINISTRATION

Instructions for proper use

The following statements apply to Gentamicin-POS® unless otherwise prescribed by your physician. Please observe these instructions for use, otherwise you will not fully benefit from Gentamicin-POS®. Apply approximately a 1 cm strip of ointment (= 0.1 mg of gentamicin sulfate) 2 – 3 times daily into the conjunctival sac.

Gentamicin-POS® is applied into the conjunctival sac. Open the tube, lean your head back slightly, and apply a 1 cm strip of ointment into the conjunctival sac. Close the eyes slowly. After use, close the tube carefully. Treatment with Gentamicin-POS® should normally not extend beyond a period of 2 weeks, or maximally 3 weeks. The exact duration of Gentamicin-POS® therapy should be based on the

physician's judgement when all factors including efficacy, severity of symptoms, and potential side-effects are considered.

MODE OF ADMINISTRATION
For ophthalmic use only

CONTRAINDICATIONS
In hypersensitivity to gentamicin or any of the ingredients (White soft paraffin, liquid paraffin, wool fat).

Contact lenses should not be worn during the treatment with Gentamicin-POS.

WARNINGS AND PRECAUTIONS
Contact lenses should not be worn during treatment with Gentamicin-POS®.
Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms including fungi. Bacterial resistance to gentamicin may also develop. If purulent discharge, inflammation or pain becomes aggravated, the patient should discontinue use of medication and consult a physician. If irritation or hypersensitivity to any component of the drug develops, the patient should discontinue the use of this preparation and appropriate therapy should be instituted.
Safety and effectiveness for use of Gentamicin-POS® eye ointment in children less than six years of age have not been established.

Ophthalmic ointment may retard corneal healing.

Special warnings
Vision will be impaired when applying Gentamicin-POS® eye ointment. Therefore you will not be able to react rapidly and purposefully in the case of unexpected and suddenly occuring events. Do not drive any vehicle or operate machines during this time.
Working persons and drivers should use Gentamicin-POS® eye ointment only at night.

DRUG INTERACTIONS
Not known.

PREGNANCY AND LACTATION
Even though no risk was observed in humans after ophthalmological use of Gentamicin-POS® eye ointment, a very careful benefit-risk analysis by the physician should justify the application of the drug, especially in the first three months of pregnancy.

ADVERSE REACTIONS
If you notice any unwanted effects not mentioned in this leaflet or if you are unsure about the effects of this product, please inform your doctor or pharmacist. Non-specific conjunctivitis, conjunctival

epithelial defect and conjunctival hyperemia. In rare cases the sensation of temporary burning in the eyes has been reported. In very rare cases mydriasis of the treated eye has been reported.

If side-effects occur, please stop applying Gentamicin-POS® and consult your ophthalmologist soon.

OVERDOSAGE AND TREATMENT
No signs of systemic effects have been observed after topical ophthalmological application of Gentamicin-POS®, due to its poor penetration. Pharmacological experiments with rabbits showed that topically applied gentamicin is well tolerated even in high dosages and long-term treatment.

If a shorter dosing interval is considered necessary due to the severity of the disease (see section Dosage and Administration), it should be taken into account that in individual cases defects (ulcerations) of the conjunctiva may occur. In such cases, the dose should be reduced or the administration of the medicinal product should be discontinued. If necessary, further treatment with another antibiotic is required.

STORAGE CONDITIONS
Do not store above 25° C.
Keep out of the reach of children!
Use before the expiration date (imprinted on the packaging carton). Do not use beyond this date.

AVAILABILITY OF DOSAGE FORMS
2.5 g eye ointment

AVAILABLE PACK SIZE
1 x 2.5 g

MANUFACTURER
URSAPHARM Arzneimittel GmbH
66129 Saarbrücken/Germany

Diimport dan diedarkan oleh:
Pharmaforte (M) Sdn Bhd
2, Jalan PJU 3/49
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47810 Petaling Jaya

DATE OF REVISION
18 December 2020

Use of topical gentamicin preparations in closed hospital settings is actively discouraged