

Kunde:	Pharmaforte (M) Sdn Bhd	Lackierung:	/
Produkt:	FS Gentamicin-POS® 5 ML MY	Lackaussparung:	☐ /
Art.-Nr.:	90.xxxx	Pharmacode:	xxxx
Format:	148 x 210 mm (Plano)	Zusatzspezifikation:	/
Blindenschrift (FS):	JA / NEIN	Sonstiges:	/
Material:	Offset 60 g/qm (UPM Fine, Fa. Nordland)		
Kleber (ET):	/	Farbtoleranz vorhanden:	JA / NEIN Nr.: FTK_UPH_
Farbe 1:	☒ Schwarz (1/1-fbg)	Farbtoleranz fertigen:	JA / NEIN Nr.: FTK_UPH_
Farbe 2:	☐ /	(6-fache Ausfertigung)	
Farbe 3:	☐ /		
Farbe 4:	☐ /	Korrekturabzug Nr.:	2 (Mock-up)
Farbe 5:	☐ /	Erstellt:	10.01.2018 A. Winter
Farbe 6:	☐ /	Freigabe Kunde:	
Farbe 7:	☐ /	Endfreigabe/Gut zum Druck:	

Gentamicin-POS® EYE DROPS

Gentamicin Sulfate 5.0mg/ml

Antibacterial Agent

PRODUCT DESCRIPTION

Gentamicin-POS® eye drops (5.0 mg/ml gentamicin sulfate) is a clear, colourless solution available as 5 ml solution filled in plastic bottles with dropping inserts and caps. Gentamicin-POS® is an antibacterial eye drops.

PHARMACOLOGY

Pharmacodynamics

Gentamicin belongs to aminoglycoside class of antibiotic, which interfere both in the resting stage in the proliferation stage of the sensitive germs with the protein synthesis on the ribosomes. Gentamicin binds to the 30S-subunit of the bacteria ribosome, which leads to 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 drops 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.

DOSAGE AND ADMINISTRATION

Instill 1 drop 4 - 6 times daily into the affected eye.

Unscrew the cap covering the nozzle, with a finger retract the lower eye lid until the inner red, moist surface is exposed. Tilt your head back, invert the bottle and gently squeeze out the prescribed number of drops onto the exposed surface of the lower lid avoiding any contact of the bottle with eye or skin. Close the bottle carefully after use.

MODE OF ADMINISTRATION

For ophthalmic use only.

CONTRAINDICATIONS

In hypersensitivity to gentamicin or any of the ingredients.

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 drops in children less than six years of age have not been established.

DRUG INTERACTIONS

Not known.

PREGNANCY AND LACTATION

Even though no risk was observed in humans after ophthalmological use of Gentamicin-POS® eye drops, 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

Irritation, stinging, itching and dermatitis. Non-specific conjunctivitis, conjunctival epithelial defect and conjunctival hyperemia. In rare cases the sensation of temporary burning in the eyes has been reported.

OVERDOSAGE

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.

STORAGE CONDITIONS

Do not store above 30°C.

AVAILABILITY OF DOSAGE FORMS

5mL

AVAILABLE PACK SIZE

1 x 5mL

MANUFACTURER

URSAPHARM Arzneimittel GmbH
66129 Saarbrücken/Germany

DATE OF REVISION

5 January 2018