URSAPHARM

Kunde:	Export MY - Pharmaforte (M) Sdn Bhd	**Lackierung:**	/		
Produkt:	PB Dexa-Gentamicin 5 ML MAL/SGP	**Lackaussparung:** ☐	/		
Art.-Nr.:	32.1040	**Pharmacode:**	1411		
Format:	148 x 210 mm (Plano)	**Zusatzspezifikation:**	/		
~~**Blindenschrift (FS):**~~	~~JA / NEIN~~	**Sonstiges:**	/		
Material:	Offset 60 g/qm (UPM Fine, Fa. Nordland)	**Kleinste Schriftgröße:**	**8 Pt**		
~~**Kleber (ET):**~~	/	**Farbtoleranz vorhanden:**	~~JA~~ / NEIN	Nr.: FTK_UPH_	
Farbe 1: ■	Schwarz (1/1-fbg.)	**Farbtoleranz fertigen: (6-fache Ausfertigung)**	~~JA~~ / NEIN	Nr.: FTK_UPH_	
Farbe 2: ☐	/				
Farbe 3: ☐	/				
Farbe 4: ☐	/	**Korrekturabzug Nr.:**	3 (Mock-up)		
Farbe 5: ☐	/	**Erstellt:**	11.02.2021	C. Staab	
Farbe 6: ☐	/	**Freigabe Kunde:**			
Farbe 7: ☐	/	**Endfreigabe/Gut zum Druck:**			

DEXA-GENTAMICIN™ EYE DROPS

Dexamethasone sodium phosphate 1.00 mg/mL and Gentamicin sulphate 5.00 mg/mL
Antiallergic, anti-inflammatory and anti-infective agent

PRODUCT DESCRIPTION

Dexa-Gentamicin™ eye drops (1.0 mg/ml Dexamethasone sodium phosphate and 5.0 mg/ml Gentamicin sulphate) is a clear, colourless solution available as 5 ml solution filled in plastic bottles with dropping inserts and caps.

PHARMACOLOGY

Pharmacodynamics

Antibiotic

The bactericidal action of Gentamicin is based on an irreversible inhibition of the bacterial protein synthesis. Gentamicin elicits rapid bacterial action by acting directly on the bacterial ribosome, where it disrupts the normal cycle of ribosomal function. Additionally, Gentamicin includes misreading of the genetic code of the mRNA template, leading to incorporation of incorrect amino acids into the growing polypeptide chain.

Corticosteroid

The corticosteroid's method of action is not yet completely known. The corticosteroids are thought to act by controlling the rate of synthesis of proteins important for chemotactic and immunologic reactions. Modifications of the leukocyte's and macrophage's functions seem to have an influence on the suppression of inflammatory and allergic reactions.

Pharmacokinetics

Antibiotic

Systemically available Gentamicin has a half-life of plasma of 2 to 3 hours in healthy adults and is excreted unchanged by the kidneys. Topically applied, Gentamicin is absorbed by conjunctiva and cornea and is detectable in the aqueous humour 15 minutes after application. Using Gentamicin on intact mucous membranes of the eye, no detectable amounts of Gentamicin are to be expected in serum.

Corticosteroid

Dexamethasone sodium phosphate and Dexamethasone poorly penetrate an intact corneal epithelium. The penetration is significantly elevated in eyes with inflamed or lesioned mucosal membranes. Systemically absorbed Dexamethasone is bound to proteins to 80 %. It is excreted by the kidneys (as glucuronid) with a half-life of 3 to 4 hours.

INDICATIONS AND CLINICAL USE

Dexa-Gentamicin™ is indicated in infections of the anterior eye including conjunctivitis, keratitis, blepharitis, and hordeolum, caused by gentamicin-sensitive pathogens; allergic inflammation of the anterior eye with bacterial super-infection.

DOSAGE AND ADMINISTRATION

Treatment with Dexa-Gentamicin™ should normally not extend a period of 2 weeks, or maximally 3 weeks. The exact duration of Dexa-Gentamicin™ therapy should be based on the physician's judgement when all factors including efficacy, severity of the symptoms and potential side effects are considered.

1 drop is administered 4-6 times daily into the conjunctival sac.

Unscrew the cap covering the nozzle. With a finger retract the lower eyelid 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

Hypersensitivity to one of the ingredients (see composition), herpes corneae superficialis, injuries and ulceration's of the cornea, closed and open-angle glaucoma, tuberculous or fungal infections of the eye.

WARNINGS AND PRECAUTIONS

Contact lenses should not be worn during treatment with Dexa-Gentamicin™.
Pediatric use: Safety and effectiveness of the eye drops in children below the age of 8 have not been

established yet.
Cushing's syndrome and/or adrenal suppression associated with systemic absorption of ocular dexamethasone may occur after intensive or long-term continuous therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (including ritonavir and cobicistat). In these cases, treatment should be progressively discontinued.

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinpathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

DRUG INTERACTIONS
Prolonged use of topical antibiotics or corticosteroids may give rise to overgrowth of nonsusceptible microorganisms and fungi. Should this occur, of if irritation or hypersensitivity to Dexa-Gentamicin™ eye drops develops, discontinue use of this preparation and institute appropriate therapy.
Cross-allergenicity among aminoglycosides or corticosteroids has been demonstrated.
CYP3A4 inhibitors (including ritonavir and cobiscitat): may decrease dexamethasone clearance resulting in increased effects and adrenal suppression/Cushing's syndrome. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid effects.

PREGNANCY AND LACTATION
There are no controlled clinical data about the use of Dexa-Gentamicin™ in pregnancy and lactation. Therefore, it should only be used after a very careful benefit-risk analysis of the treating physician.

Although there is no confirmed knowledge concerning the teratogenic effects of Dexa-Gentamicin™, accurate diagnosis is imperative for any treatment. After ophthalmologic use, Dexamethasone may be absorbed systemically and therefore pass into mother's milk during lactation.

ADVERSE REACTIONS
Endocrine disorders
Not known: Cushing's syndrome, adrenal suppression

Eye Disorders
In rare cases the sensation of temporary burning in the eyes has been reported. Prolonged use may result in glaucoma and cataract formation.

Adverse effects due to ophthalmic corticosteroids include increased intraocular pressure; glaucoma; infrequent optic nerve damage; defects in visual acuity and visual fields; posterior subcapsular cataract formation; delayed wound healing; filtering blebs following cataract surgery; secondary ocular infection from pathogens including herpes simplex.

Corticosteroid-containing ophthalmic preparations can also cause acute anterior uveitis or perforation of the globe. Mydriasis, loss of accommodation and ptosis has occasionally been reported following topical corticosteroid therapy. Allergic sensitization may occur with ophthalmic antibiotics.

Transient eye irritation has been reported with ophthalmic Gentamicin sulfate.

Not known: Vision, blurred

OVERDOSAGE
Overdosing or intoxication is not to be expected after topical ophthalmological application of Dexa-Gentamicin™ due to its poor penetration.

STORAGE CONDITIONS
Do not store above 25°C.

AVAILABILITY OF DOSAGE FORMS 5 mL

AVAILABLE PACK SIZE 1 x 5 mL

MANUFACTURER
Ursapharm Arzneimittel GmbH, 66129 Saarbrücken/Germany

DATE OF REVISION
February 2020

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