

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

PYRICORT EYE DROPS

GENTAMICIN SULPHATE AND DEXAMETHASONE SODIUM PHOSPHATE EYE DROPS

Composition:

Gentamicin.....0.3% w/v
(3000 units/ml)

(As Gentamicin Sulphate)
Dexamethasone..... 0.1% w/v
(As Dexamethasone Sodium Phosphate)
Benzalkonium Chloride NF.....0.01% w/v
(As preservative)
Aqueous buffered vehicle.....q.s.

Description:

A clear, colourless solution in labeled LDPE vial.

Pharmacodynamics:

Gentamicin is an aminoglycoside antibiotic active against a great variety of Gram-positive and Gram-negative pathogenic microorganisms.
Dexamethasone is a potent corticosteroid with antiallergic, antiexudative and antiproliferative properties, which inhibits the inflammatory response caused by immunological, mechanical or chemical agents.

Pharmacokinetics:

Dexamethasone, like other corticosteroids, is absorbed rapidly after oral administration and has a biological half-life of about 190 minutes. Sufficient absorption may occur after topical application to the skin and eye to produce systemic effects. Intraocular penetration of dexamethasone occurs in significant amounts and contributes to the effectiveness of dexamethasone in anterior segment inflammatory disease.

Topical application of gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µg/ml.

> 90% Gentamicin is excreted in the urine by glomerular filtration, < 10% is bound to plasma protein.

T½ = 2 - 3 hours in individuals with normal kidney function, but can be increased in cases of renal insufficiency.

Indication:

Topical treatment of infections of the anterior pole of the eye with inflammatory complications caused by germs sensitive to gentamicin. Infective and allergic conjunctivitis and blepharoconjunctivitis. Keratitis (superficial, deep, phlyctenular, sclerosing, acne rosacea). Scleritis and episcleritis.

Recommended Dose:

Normally, treatment is initiated with one or two drops instilled every 4 hours (in severe infections, the frequency of instillation can be increased), which is reduced according to the clinical evolution.
It is not recommended to use this product for more than 14 days, unless otherwise advised by physician.

Route of Administration:

For Ocular use only.

Contraindications:

Glaucoma simplex. Hypersensitivity to any of the components of the formula. It is not recommended for viral or fungal infections, or ocular tuberculosis.

Warnings and precautions:

Precautions:

Prolonged use of topical antibiotics may give rise to overgrowth of non susceptible organisms, including fungi bacterial resistances to gentamicin may also develop. If purulent discharge inflammation or plain becomes aggravated. The patient should discontinue use of the medication and consult a physician.

If irritation or hypersensitivity to any component of the drug develops, the patient should discontinue use of this preparation, and appropriate therapy should be instituted.

Pyricort ED may increase intraocular pressure glaucoma. Therefore, it must be administered only under physician prescription and supervision.

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

This preparation contains Sodium Metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites.

Warnings:

This product contains Benzalkonium chloride; therefore soft contact lenses should not be worn until at least 20 minutes following the instillation of the drops.

Interactions with other medicaments:

Have not been described

Pregnancy and Lactation:

Safety for use in pregnancy and lactation has not been established. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth with retardation. There may therefore be a very small risk of such effects in human pregnancy. Use only when it is considered essential by the physician.

Safety for use in pregnancy and lactation has not been established. Gentamicin should only be used in pregnancy or lactation when considered essential by the physician, after careful assessment of the potential risks and benefits.

Side Effects

Irritation, pain, itching, and burning may occur, which could sometimes require discontinuation of the treatment. Prolonged treatment with corticosteroids may increase intraocular pressure.
Corneal infection caused by fungi or other non-susceptible microorganisms to the antibiotic may occur, in which case medication should be discontinued and appropriate measures taken.

Symptoms and treatment of Overdose:

Due to the characteristics of this preparation intended for topical use, no toxic effects are expected with the use of this product at the recommended dose. In case of overdose or accidental ingestion of the contents of a bottle, particularly in children, symptoms of sedation requiring symptomatic treatment may occur. In these cases consult physician or a Poison Control Center.

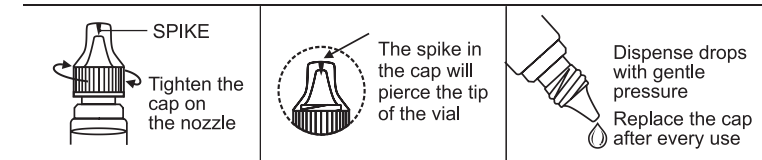
Storage: Store in a dry place, below 30°C and protect from light.

Shelf Life: 18 months from date of manufacture for unopened vial and one month from the date of opening the vial.

Presentation: Pack of 5ml in LDPE vial.

Date of preparation: July 2025

MODE OF USE



Manufactured by:

FDC Limited

Regd. Office : B-8 M.I.D.C. Area, Waluj
Dist. Aurangabad 431 136, India.

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EXPORT				
RA				
QA				
R&D (F)				
Packaging Development Department	Approved by			HISTORY: New Artwork prepared for first time for Malaysia.
	Checked by			

FDC Limited		LEAFLET		Mini Pharma Code No.: 442 FRONT/243 BACK	
Size	110mm x 144mm - Artwork Same Size	Folded Size		Unfolded Size	
No. of Folds		GSM	60 GSM	Paper	Maplittho Paper
Specifican No.		Colour	BLACK	Supercedes A/W Code
Location	Waluj - Country : Malaysia	Artwork Code	W1PTLL01AESMY	Prepared On:	3-11-12