

# PYRICORT EYE DROPS

Gentamicin/ Dexamethasone (0.3% w/v / 0.1% w/v)

## What is in this leaflet

1. What Pyricort is used for
2. How Pyricort works
3. Before you use Pyricort
4. How to use Pyricort
5. While you are using it
6. Side effects
7. Storage and Disposal of Pyricort
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What Pyricort is used for

Pyricort Eye Drop helps in the treatment of a range of bacterial infections.

## How Pyricort works

Pyricort Eye Drop belongs to a group of medicine called the aminoglycoside antibiotics. The medicine stops bacterial growth thus preventing or treating the infection.

## Before you use Pyricort

### - When you must not use it

- If you are allergic to Gentamicin or Dexamethasone, or any of the ingredients in the product

## Pregnancy and lactation

Gentamicin should only be used in pregnancy or lactation when considered essential by the physician, after careful assessment of the potential risks and benefits.

### - Before you start to use it

### 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. Discontinue use of the medication and consult a physician.
- If irritation or hypersensitivity to any component of the drug develops, the individuals should discontinue use of this preparation, and appropriate therapy should be instituted.

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

### 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.
- 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 individuals. Do not use if known to be hypersensitive to bisulphites.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

## How to use Pyricort

### - How much to use

Adult: Instill 1-2 drops into the affected eye every four hours as required. (in severe infections, the frequency of instillation can be increased), which is reduced according to the clinical evolution.

Children: No dosage adjustment required in children.

### Instructions for use

- First wash your hands
- Avoid touching the eye (or any other surface) with the tip of the bottle
- If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting
- These drops are supplied as a sealed bottle with a spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle

- Tilt your head back and look at the ceiling. Pull the lower eyelid gently downwards. Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye

- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute
- Repeat for the other eye if necessary
- Replace and tighten the cap immediately after use.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Continue taking Pyricort for as long as your doctor recommends.

### - If you forget to use it

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal scheduled dose.

### - If you use too much (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.

## While you are using it

### - Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Pyricort. Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give PYRICORT to anyone else, even if they have the same symptoms or condition as you. Remove contact lenses before using the eye drops and wait at least 15 minutes before reinserting.

- Things to be careful of

*Driving and using machines*

No effects on ability to drive and use machines have been reported. However, do not drive or operate machines if you experience blurred vision after using as eye drops. Wait until your vision clears before driving or operating machines.

**Side effects**

Like all medicines, PYRICORT can cause side effects, although not everybody gets them. Irritation, pain, itching, and burning may occur, which could sometimes require discontinuation of the treatment. Prolonged treatment with corticosteroids may increase pressure in the eye. Eye 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. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

**Storage and Disposal of Pyricort**

- Storage

Keep out of the reach and sight of children.  
Store in a dry place, below 25°C and protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like

A clear, colourless solution in labelled LDPE vial.

- Ingredients

- Active ingredient(s)  
Gentamicin sulphate (0.3W/V)  
Dexamethasone sodium phosphate (0.1W/V)

- Inactive ingredients  
Disodium edetate, Sodium dihydrogen phosphate dehydrate, Sodium phosphate, Sodium metabisulphate, Creatinine, Benzalkonium chloride, Water for injection.

- MAL number(s):

MAL12020006AZ

**Manufacturer**

FDC LIMITED,  
Plot No. B-8, M.I.D.C. Industrial Area,  
Waluj, Aurangabad, 431 136,  
Maharashtra State, India.

**Product Registration Holder**

UNIMED SDN BHD  
53, Jalan Tembaga 5/2B  
Bandar Sri Damansara  
52200, Kuala Lumpur  
Malaysia.

**Date of revision**

20/06/2019

→ **Serial Number:**

NPRA(R4/1)100119/00006