DEXA-GENTAMICIN EYE DROPS

Dexamethasone Phosphate/ Gentamicin Sulphate (1mg/5mg per 1ml)

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What Dexa-Gentamicin is used for

Dexa-Gentamicin is used for bacterial infections associated with allergic reaction or inflammation of the eyes or eyelids.

How Dexa-Gentamicin works

Dexa-Gentamicin contains active ingredients of dexamethasone and gentamicin.

Dexamethasone is in corticosteroid group which help to reduce inflammation, redness and itchiness, while gentamicin is an antibiotic that kills certain bacteria that caused infections.

Before you use Dexa-Gentamicin

- When you must not use it

Do not use Dexa-Gentamicin if:

- you are allergic to dexamethasone, gentamicin sulphate or any ingredients of this medicine (listed in Product Description)
- you have viral, tuberculous or fungal infection or ulceration of the eyes
- you have increased pressure in the eyes (glaucoma)

Consult your doctor before using Dexa-Gentamicin.

- Before you start to use it

Please tell your doctor if you have any medical illness.

Not to be used in children below 8 years old.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine. Dexa-Gentamicin must only be used during pregnancy if the benefits is more than the risks to the fetus. Dexamethasone is secreted into breast milk and may affect your baby. Your doctor will discuss the risk and benefits of breast feeding while you're using Dexa-Gentamicin.

- 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, for example:

> - ritonavir or cobicistat (medicine used in HIV treatment)

How to use Dexa-Gentamicin

Unscrew the cap covering the nozzle. Tilt your head back, gently pull down the lower eye lid and apply one drop into the conjunctival sac by gently squeezing the bottle. Slowly close your eyes. Close the bottle carefully after use.

- How much to use

Instill 1 drop into the affected eye.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use 4-6 times daily or as directed by your doctor or pharmacist.

- How long to use it

Use Dexa-Gentamicin for the duration that the doctor recommends. The treatment with Dexa-Gentamicin normally will not extend beyond two weeks or maximally 3 weeks.

- If you forget to use it

Instill the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to instill the medicine and skip the missed dose. Do not instill a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharameists treating you that you are using Dexa-Gentamicin.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

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Do not give Dexa-Gentamicin to anyone else, even if they have the same symptoms or conditions as you.

- Things to be careful of

Remove contact lenses before using Dexa-Gentamicin eye drops.

If irritation or hypersensitivity to Dexa-Gentamicin eye drops occurs, stop using this medicine immediately and see doctor as soon as possible.

Driving and using machines

Dexa-Gentamicin may distort your vision temporarily. Make sure you know how you react to it before you drive a car, or operate machinery.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Please consult your doctor or pharmacist for further information.

Side effects:

- Increase of pressure in the eye
- Dilated pupils
- Drooping of the upper eyelid
- Eye irritation

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

Storage and Disposal of Dexa-Gentamicin

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and folding carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

You can use Dexa-Gentamicin up to 4 weeks after first opening the bottle.

- Disposal

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Dexa-Gentamicin is a clear, colourless eye drops which are filled in a plastic bottle with dropping insert and screw cap. Each bottle of Dexa-Gentamicin contains 5ml of solution.

- Ingredients

- Active ingredient(s)

Each ml contains:

1mg of Dexamethasone Sodium Phosphate and 5mg of Gentamicin Sulphate (equivalent to 3mg/ml gentamicin)

- Inactive ingredients

The other ingredients are benzalkonium chloride (preservative), sodium chloride, potassium dihydrogen phosphate, dipotassium, hydrogen phosphate, water for injections.

<u>- MAL number:</u> MAL19988443AZ

Manufacturer

Ursapharm Arzneimittel GmbH Industriestraβe 66129 Saarbrücken/ Germany

Product Registration Holder

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