BETAGEN EYE/EAR DROPS®

Gentamicin Sulphate / Betamethasone (0.3% w/v / 0.1% w/v)

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What Betagen is used for

Betagen Eye/Ear Drops is indicated for the inflammatory conditions of the eye or ear where there is bacterial infection.

Ask your doctor if you have any questions about why Betagen has been prescribed for you. Your doctor may have prescribed it for another purpose.

How Betagen works

Betamethasone is a steroid that helps to decrease the swelling, redness and itching.

Gentamicin belongs to the aminoglycoside class of antibiotics that works by stopping the growth of bacteria.

Before you use Betagen

- *When you must not take it*

Do not use Betagen if you are allergic to:

- Betamethasone or other corticosteroid
- Gentamicin sulphate or other aminoglycosides
- any of the other ingredients of this medicine

Do not use Betagen if you have fungal, viral or bacterial infection of the ear or eye.

Do not use if you have hole in the ear

- *Before you start to use it*

Talk to your doctor, pharmacist or nurse before using Betagen if you have:

- Clouding of eye lens
- Diabetes
- Diseases which cause thinning of the eye layers
- Family history of increased eye pressure
- Local irritation or hypersensitivity (allergy) to any of the ingredients of the product

The abrupt discontinuation of the product may cause a withdrawal syndrome.

The use of the bottle by more than one person may lead to spread of the infection.

- *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.

Some medications and Betagen may interfere with each other. These includes:

- Medicines to treat increased eye pressure
- Anticholinergic such as atropine
- Medicines for HIV such as cobicistat

How to use Betagen

- *How much to use*

Always take this medicine exactly as your doctor or pharmacist has told you. 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.

The recommended dose is:

Eye:

1 drop to the eye(s) every 4 hours for mild to moderate infections

1 drop to eye(s) every hour for severe infections

Ear:

3 or 4 drops to the ear canal 3 times a day, with dosage gradually being decreased as the inflammation subsides

- *When to use it*

Always use Betagen eye/ear drops at the doses, at a dose and in a way, prescribed by the attending doctor.

- *How long to use it*

The duration of topical therapy depends on the type and severity of the disease.

Continue taking Betagen for as long as your doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

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

- *If you use too much (overdose)*

If you have instilled an excessive amount in the eye/eyes, Betagen can be rinsed out with tempered water.

If you have instilled an excessive amount in the ear, you may turn your head in a way to let the excessive liquid run out of the ear.

While you are using it

- *Things you must do*

Before you start using the product, make sure that the protective strip between the cap and the bottle is not broken. Wash your hands and unscrew the cap.

- *Things you must not do*

The treatment discontinuation should be determined by the attending doctor. The treatment with Betagen should be discontinued by gradually decreasing the frequency of application or of the dose.

- *Things to be careful of*

As with all eye drops, transient blurring of vision or other disturbances may affect the ability to drive or use machines. After the instillation of Betagen in the eye, you should wait until your vision clears, before you start operating machines or driving.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

There are reports of side effects which may be related with the use of the medicinal product, but they are mild and subside quickly after the treatment discontinuation.

Eye:

- Retard corneal healing if used frequently or intensive use
- Increase risk of adrenal suppression in children
- Temporary mild blurred vision
- Less frequently are burning, stinging, redness and watering of eyes

- Reported rarely are corneal thinning, increased eye pressure, clouding of eye lens, optic nerve damage and secondary eye infection.

Ear:

- Burning or stinging of the ear

Betagen contains a corticosteroid (betamethasone), which may lead to elevation of the pressure in the eye during prolonged use.

The long-term treatment with topical corticosteroids may lead to perforation (corneal breakdown) in diseases associated with thinning of the cornea.

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.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Betagen

- *Storage*

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

Store in the original package. Keep container tightly closed. Store in a dry place below 25°C.

- *Disposal*

The bottle should be disposed of 4 weeks after opening, in order to avoid eventual infections and contaminations.

Do not use Betagen after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Ask your pharmacist how to throw away medicines you no longer use.

Product Description

-What it looks like

A clear, colourless, sterile solution.

-Ingredients

- Active ingredients:
  - Gentamicin Sulphate
  - Betamethasone Sodium Phosphate

- Inactive ingredients:
  - Disodium Hydrogen Phosphate
  - Sodium dihydrogen phosphate dihydrate
  - Sodium Chloride
  - Disodium Edetate
  - Benzalkonium Chloride 50% Solution
  - Trisodium Citrate

- *MAL number*

MAL10110027AZ

Manufacturer

Duopharma (M) Sdn Bhd
Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Duopharma (M) Sdn Bhd
Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

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