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1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information to the patient

GENTASOL 0.3 % eye drops, solution
Gentamicin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- . Keep this leaflet. You may need to read it again.
- . If you have any further questions, ask your doctor or pharmacist.
- . This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- . If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What GENTASOL is and what it is used for
2. What you need to know before you use GENTASOL
3. How to use GENTASOL
4. Possible side effects
5. How to store GENTASOL
6. Content of the pack and other information

1. WHAT GENTASOL IS AND WHAT IT IS USED FOR

The name of your medicine is GENTASOL eye drops. This medicine contains the active ingredient gentamicin which belongs to a group of medicines called antibiotics. GENTASOL is used in adults and children to treat bacterial infections in the eye and to prevent infections in an injured eye.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE GENTASOL

Do not use GENTASOL if you:

- are allergic (hypersensitive) to gentamicin, any of the other ingredients of GENTASOL (listed in section 6), or to a similar medicine containing an aminoglycoside antibiotic;
- suffer from myasthenia gravis, a disease causing muscle weakness.

Warning and precautions

Talk to your doctor or pharmacist before using GENTASOL eye drops if you:

- have any problems with your kidneys or liver and especially if you are elderly;
- have open wounds or damaged skin, as topical application to these areas may cause deafness;
- are using this medicine for a long period of time, as it may lead to skin sensitization and organism resistance;
- are using other aminoglycoside antibiotics such as erythromycin, as cross sensitivity may occur;
- are using this medicine in severe infections, as topical use of gentamicin should be supplemented with appropriate systemic antibiotic treatment;

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- are using contact lenses, as it should be removed during the period of treatment of ocular infections.

If any of these apply to you, or if you are not sure, tell your doctor.

Other medicines and GENTASOL

Please tell your doctor or pharmacist if you are taking, or have recently taken, or might take any other medicines, including medicines obtained without a prescription.

This is especially important if you are taking:

- ethacrynic acid (used in the treatment of high blood pressure and swelling);
- furosemide (used in the treatment of congestive heart failure and swelling);
- antibiotics such as cephalosporins;
- ciclosporin (used to stop the body rejecting bone marrow or organ transplants);
- amphotericin (used to treat fungal infections);
- cisplatin (used in anti-cancer therapy);
- muscle relaxants.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine. GENTASOL is not recommended for use in pregnancy or breast-feeding unless considered appropriate by your doctor.

Driving and using machines

GENTASOL may cause temporary blurred vision when used. If you are affected, do not drive or use machinery until the blurring has cleared.

GENTASOL contains benzalkonium chloride

May cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses.

3. HOW TO USE GENTASOL

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one or two drops in the infected eye up to 6 times a day. For more severe infections your doctor may tell you to use the drops more often than this. Contact lenses should be removed when treating an eye infection with these drops.

This medicine is only for ophthalmic use.

1. wash your hands prior to instillation.
2. avoid touching your eye or eyelid with the tip of the bottle.
3. squeeze one drop inside the lower lid while looking upwards.
4. put the cap back on the bottle after use.

If you swallow GENTASOL

If you, or someone else, accidentally swallows some of this medicine, contact your doctor, pharmacist or nearest hospital emergency department **immediately**.

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If you forget to use GENTASOL

Apply the next dose as soon as you remember and continue as before.

4. POSSIBLE SIDE EFFECTS

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

If you notice:

- itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty in breathing with wheeziness.

Stop using these drops and tell your doctor immediately. These may be signs of an allergic reaction.

Side effects may include:

- problem with your kidney function;
- blurred vision;
- irritation, burning, stinging, and itching of the skin (at the application site). If this occurs, stop treatment and talk to your doctor;
- super infection (a new, added infection);
- dizziness;
- tinnitus (ringing in your ears);
- this product contains the preservative benzalkonium chloride which may cause eye irritation or skin reactions and is known to discolour soft contact lenses.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system

5. HOW TO STORE GENTASOL

Keep out of the sight and reach of children.

Do not use GENTASOL after the expiry date which is stated on the carton. Do not store above 30° C. Keep the bottle in the outer pack in order to protect from light. Do not use the eye drops for more than 30 days after first opening.

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

6. CONTENT OF THE PACK AND OTHER INFORMATION

What GENTASOL contains?

The active substance is gentamicin (as Sulphate) at a concentration of 3 mg/ml.

The other ingredients are: benzalkonium chloride solution, sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium hydroxide, water for injections.

What GENTASOL looks like and contents of the pack

GENTASOL eye drops, solution is available in bottle containing 5 ml of clear solution.

This leaflet was last updated in 09/2018

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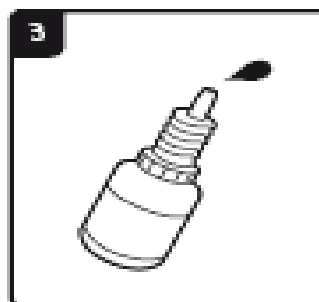
Manufacturer: Ahlcon Parenterals (I) SP-917-918, Phase-III, Ind. Area, Bhiwadi-301019, Dist. Alwar (Rajasthan)



1. With the spike: tighten the cap on the nozzle



2. The spike in the cap will pierce the tip of the bottle



3. Dispense drops with gentle pressure. Replace the cap after every use.