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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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

1. What Gentazon is and what it is used for
Gentazon eye and ear drops, solution is a compound product, which combines the anti-inflammatory and anti-allergic activities of betamethasone sodium phosphate with the broad-spectrum bactericidal effect of gentamicin sulphate. Betamethasone is a potent corticosteroid and when applied at lower doses, it achieves a strong anti-inflammatory effect. Gentamicin belongs to the aminoglycoside class of antibiotics and is active against a large number of Gram-positive and Gram-negative microorganisms.
Gentazon eye and ear drops, solution is indicated:

- For the treatment of superficial ocular inflammation and allergic conditions, when bacterial infection, caused by gentamicin-susceptible microorganisms, is presented or likely to develop: inflammation of the eyelid (blepharitis), conjunctiva (conjunctivitis), cornea (keratitis and keratoconjunctivitis), sty, inflammation of the lacrimal gland (dacryocystitis), episcleritis (superficial inflammation of the eye). It is also used in traumas (penetrating and non-penetrating), due to chemical, radiation and postoperative factors;

- For the topical treatment of inflammation of the external ear canal (external otitis) following an examination of the affected ear (the tympanic membrane should be intact), an evaluation of the hearing ability and an antibiogram showing that the infection has been caused by gentamicin-susceptible microorganisms.

2. **What you need to know before you use Gentazon**

Do not use Gentazon

- if you are allergic to the active substances (gentamicin and betamethasone) or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to any other medicine of the group of aminoglycoside antibiotics
- if you have fungal and viral infections:
  - Herpes infection of the eye or the cornea;
  - Varicella (chickenpox) or a post-vaccination reaction;
  - Tuberculous infection of the eye;
  - Acute early stages of most viral diseases of the cornea and conjunctiva;
  - Diseases with impaired integrity of the superficial layer of the cornea;
- if you suffer from glaucoma (high intraocular pressure).
- in patients with a missing or perforated tympanic membrane (ruptured eardrum).
**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Gentazon.

Gentazon eye and ear drops, solution is not intended for injecting into the eyelid or the eye.

In case of development of local irritation or reactions of hypersensitivity (allergy) to any of the ingredients of the product, its application should be discontinued immediately and appropriate treatment should be administered.

As with other antibacterial medicinal products, the prolonged use of Gentazon may result in development of microorganisms or fungi, non-susceptible to the antibiotic. In case of development of such an infection, initiation of appropriate treatment is recommended.

Gentamicin (one of the active ingredients of Gentazon) should be kept for the treatment of severe, vision-threatening infections and inflammation of the eye and adjacent tissues, and infections caused by microorganisms unsusceptible to the more commonly used antibiotics. If a clinical effect has not been achieved after the recommended course of treatment, a culture should be performed for determining the antibacterial susceptibility of the causative agent.

Gentamicin, as representative of the aminoglycoside class of antibiotics, exhibits a toxic effect on the ear. If reduced hearing develops, the use of the product should be discontinued. The risk of a toxic effect on the eighth cranial nerve should be taken into consideration.

In its composition, Gentazon contains a corticosteroid (betamethasone), which may lead to elevation of the intraocular pressure during prolonged use. If the product is to be applied for ten and more days, monitoring of the intraocular pressure and examining of the eyegrounds (*fundus oculi*) are recommended, especially in predisposed patients with familial history of open-angle glaucoma, severe short-sightedness and diabetes mellitus.
The use of Gentazon in patients with glaucoma (high intraocular pressure) requires frequent measurements of the intraocular pressure. If it increases, the treatment with Gentazon should be stopped. The long-term treatment with topical corticosteroids may lead to perforation (corneal breakdown) in diseases associated with thinning of the cornea. In case of a deep ulcer in the cornea, it is not recommended to start the treatment with a combined product containing an antibiotic and a corticosteroid. It would be better to start with a pure antibiotic and to add a corticosteroid later, in order to reduce the likelihood of scar formation.

In acute suppurative processes, corticosteroids may mask the development of an infection or the worsening of an available infection. The long-term use of systemic or topical corticosteroids may cause the development of a posterior subcapsular cataract (a type of cataract).

The long-term and/or intensive treatment with the product may lead to development of some side effects (suppression of the hypothalamic-pituitary-adrenal axis or cushingoid syndrome).

The abrupt discontinuation of the product may cause a withdrawal syndrome. Children receiving a long-term treatment with systemic or topical corticosteroids should be monitored for abnormalities in growth and development. In children, the resorption of topical corticosteroids may be higher in percentages, thus, making them exposed at a higher risk of systemic toxicity.

It is better to avoid the simultaneous or consecutive application of systemic and topical preparations with toxic effects on the kidneys and/or the ears.

With regard to limiting the passage into systemic circulation, after the instillation of Gentazon in the eye, it is necessary to press at the inner eyelid corner (in the region of the lacrimal canal) with the index finger for 1-2 minutes.

Gentazon contains benzalkonium chloride as preservative, which may induce irritation of the eyes. It may precipitate on the contact lens surface or decolourise it.
The patients should be informed not to wear contact lenses if an eye infection is available.
When using the product for the treatment of ear inflammation, a very accurate medical evaluation and monitoring of the state are recommended, in order to enable the administering of additional therapeutic measures, if needed (systemic antibiotics, surgical intervention, etc.).
It is necessary to observe the hygienic requirements with the use of the product, in order to avoid contamination of the solution or microbial cross contamination during simultaneous treatment of eye and ear diseases. Two individual bottles should be used.
The use of the bottle by more than one person may lead to spread of the infection.
Do not use after the expiry date which is stated on the pack of the product.

**Other medicines and Gentazon**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
There are no data of performed studies on the interactions of Gentazon, containing gentamicin and betamethasone for ocular and auricular use, with other medicinal products.

**Gentazon with food, drink and alcohol**
No interactions have been established.

**Pregnancy, breast-feeding and fertility**
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 this medicine.
If you are pregnant, making attempts to get pregnant or breast-feeding at present, Gentazon should be administered with caution and by your attending physician’s prescription only.
Driving and using machines
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 Gentazon in the eye, you should wait until your vision clears, before you start operating machines or driving. There are no known effects of Gentazon on the ability to drive and use machines after its application in the ear. It is unlikely to have an effect.

Gentazon contains benzalkonium chloride
Gentazon eye/ear drops contains a preservative (benzalkonium chloride), which may induce irritation of the eyes. If you wear contact lenses, it may precipitate on the lens surface or decolourise it. Therefore, you should not wear contact lenses, whilst you are using Gentazon. It is important to know, that you should not wear contact lenses in case of available eye infection.

3. How to use Gentazon
Always take 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:
Adults, adolescents and children over 8 years of age:
Ocular use
The dosage is determined depending on the individual patient’s needs. The usual dose is 1-2 drops instilled 3-4 times daily in the conjunctival fold of the affected eye/eyes. In the acute stage of the disease, the dose may be increased to 2 drops every 1-2 hours; after the achievement of a therapeutic response, the frequency of application may be decreased. The duration of topical therapy depends on the type and severity of the disease.
During simultaneous application with any other product for ocular use, the interval between the applications of the two products should be at least 10 minutes. Keeping hygiene during the instillation of the drops is of importance. Avoid the contact between the tip of the bottle and the eye or surrounding objects, since the tip may be contaminated, thus leading to development of eye infection with serious sequels for the eye, even to loss of vision. Always wash your hands before using the bottle! If you think that your product is contaminated, contact your doctor before continuing the application of this eye drops.

Instructions for use

1. 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.

2. Tilt your head slightly backwards and pull the lower eyelid downwards. Thus, a pouch is formed between the eyelid and the eye. The eye drop will fall just into this place.

3. Hold the bottle downwards. Put its tip close to the eye. Use a mirror, if helpful.

4. Pay attention not to touch the tip of the bottle to the eye, eyelid or adjacent surfaces. Press carefully the bottle base to let fall a drop of Gentazon. Only a slight pressure on the bottom is needed.

5. After you have instilled Gentazon, close the eyelid and by using your finger, press at the corner of your eye near your nose. This will prevent Gentazon from passing into the nose or running out.

6. If it is necessary to apply the eye drops in both eyes, repeat all previously described steps for the other eye.

If the eye drop fails to fall in the eye, try again. Use this bottle of Gentazon for your eyes only!
**Auricular use**

The initial dose is 3-4 drops, instilled 2 – 4 times daily in the ear canal. Upon achieving a therapeutic response, the dose may be reduced, and after curing, the treatment should be discontinued.

The medicinal product may also be applied by insertion of an ear tampon, soaked with the solution, in the external ear canal. This tampon should be soaked with the solution every 4 hours and replaced every 24 hours.

In case of application of more than one product for auricular use, an interval of 10 – 15 minutes should be allowed between the individual instillations.

**Instructions for use**

1. Before you start using the product for the first time, make sure that the protective strip between the cap and the bottle is not broken.
2. The person, who will instill Gentazon should wash her/his hands with water and soap.
3. Clean carefully any discharge that may be removed easily from the external ear. **Do not insert any object or tampon in the internal canal of the ear.** Hold the bottle with Gentazon in your hand for one – two minutes, to warm up the solution.
4. The person, who will be instilled with Gentazon should lie on one side, with her/his inflammed ear upwards.
5. Unscrew carefully the cap and hold the bottle downwards, between the thumb and the middle finger.
6. Put the tip of the bottle close to the ear canal. **Pay attention not to touch the lobe of the ear, ear canal, adjacent tissues or surfaces with the tip of the bottle!** This may contaminate the ear drops.
7. By using your index finger, press the bottom of the downturned bottle, to let fall a drop of Gentazon, when necessary.

8. In infections of the external ear, whilst the patient is in a lying position, the person who will instill the drops, should pull the lobe of the ear carefully downwards and backwards. This will allow the ear drops to pass through the ear canal.

9. The patient should remain in a lying position for at least 5 minutes.

10. If it is necessary to apply the drops in the other ear, repeat the steps from 3 to 9.

_Use this bottle of Gentazon for your ears only!_

_If the ear drop fails to fall in the ear, try again._

In chronic diseases of the ear/ears, the treatment should be discontinued through gradually decreasing the frequency of application of the medicinal product.

**If you use more Gentazon than you should**

Always apply Gentazon eye/ear drops at the doses, at a dose and in a way, prescribed by the attending physician.

Long-term treatment or application of doses, higher than the prescribed ones, may lead to development of symptoms requiring symptomatic treatment.

If you have instilled an excessive amount in the eye/eyes, Gentazon 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.
If you forget to use Gentazon
Do not apply a double dose to make up for a forgotten dose. Apply the dose as soon as you remember. If it is almost the time for your next dose, continue according to your usual regimen.

If you stop using Gentazon
The treatment discontinuation should be determined by the attending physician. The treatment with Gentazon should be discontinued by gradually decreasing the frequency of application or of the dose.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible 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.
The most common side effects are transient irritation, burning, reddening, mild swelling of the eyelids, abnormal sensitivity to light and blurred vision shortly after the application of Gentazon.
With the ocular use of gentamicin (one of the active ingredients of the product), allergic reactions may develop. Other gentamicin-related common side effects are non-specific conjunctivitis, superficial defects of the conjunctiva and redness.
The side effects associated with the ocular use of corticosteroids include:
Increase of the intraocular pressure (development of glaucoma), rarely, damage of the optic nerve, reduced vision and defects in the visual field;
Development of posterior subcapsular cataract (a type of cataract);
Delayed healing of superficial injuries;
Formation of cysts under the conjunctiva after surgical interventions; Secondary eye infections, including herpes infection.
There are reports that corticosteroid-containing medicinal products for topical ocular use may cause:
Anterior uveitis (inflammation of the iris);
Breakdown of the eye;
Dilatation of the pupil, disturbances in accommodation (a type of vision disorder);
Drooping of the upper eyelid (ptosis).
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. **How to store Gentazon**
Keep this medicine out of the sight and reach of children.
Store in the original package.
Store below 25°C.
The bottle should be disposed of 4 weeks after opening, in order to avoid eventual infections and contaminations.
Do not use Gentazon after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Do not throw away any 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.

6. **Contents of the pack and other information**
**What Gentazon contains**
- The active substances are 3 mg of gentamicin (as sulphate) and 1 mg of betamethasone (as sodium phosphate);
- The other ingredients (excipients) are benzalkonium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, sodium
citrate, sodium borate, sodium chloride, disodium edetate, water for injections.

**What Gentazon looks like and contents of the pack**

Eye and ear drops, solution

Clear, colourless to pale yellow liquid

Sterile white plastic bottle closed with a sterile plastic dropper applicator and sealed hermetically with a sterile screw cap fitted with a tamper-evident ring.

1 (one) bottle with a patient leaflet is inserted in a carton box.

**Marketing Authorisation Holder**

Antibiotic-Razgrad AD

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Razgrad 7200, Bulgaria

**Manufacturer**

Balkanpharma-

Razgrad AD

68 “Aprilsko vastanie” Blvd

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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