



Gentavet-G

Eye and Ear Drops 3 mg Gentamicin



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Use during pregnancy and lactation:

Safety of use of the veterinary pharmaceutical product was not detected during pregnancy and lactation. It should be used after evaluating of the benefit/risk by the veterinary physician.



**PACK
SIZE
5 ml**



Shelf Life:
**36
months**

COMPOSITION Gentavet-G Eye and Ear Drops is an almost colourless or light yellow coloured, odourless, sterile solution and each ml contains gentamicin sulfate equivalent to 3 mg gentamicin base and benzalkonium chloride as excipient. **PHARMACOLOGICAL PROPERTIES** Pharmacodynamic properties: Gentamicin is a broad spectrum antibiotic and bactericidal. It is particularly effective against fast-growing organisms. Gentamicin acts by irreversibly binding to the 30S ribosomal subunit, thus protein synthesis is inhibited in susceptible bacteria. Gram-positive and Gram-negative bacteria including Staphylococcus intermedius, coagulase-positive Staphylococcus spp. and pathogenic organisms isolated from the ears of the dogs such as Proteus mirabilis are spectrum in activity. Bacterial resistance phenotypes against gentamicin are based on three mechanisms in general: enzymatic modification of aminoglycosides, disruption of ribosomal binding and disruption of transport during membrane transition. Cross-resistance is mainly related to efflux that gains resistance to β -lactams, quinolones and tetracyclines depending on the substrate and originality of the pump. It is one of the most common mechanism of acquiring resistance in Gram negative bacteria. Active efflux pump in the plasma membrane extrudes the antibiotic from the cell. Entry of antibiotics into the cell may be disrupted and drug accumulation may decrease in the cell. Co-resistance was reported, namely it was found that gentamicin resistance genes were related to other antimicrobial resistance genes due to the other transferable genetic elements. Between 2008-2010, gentamicin-resistant bacteria isolated before the treatment of dog otitis (breaking point was determined according to ≥ 8 CLSI data (Clinical and Laboratory Standards Institute) for all isolates without Staphylococci ≥ 16 μ g/ml) was found low as 4.7% Staphylococcus spp., % 2.9 Pseudomonas and % 12.5 Proteus spp. It was reported that all Escherichia coli isolates were completely susceptible to gentamicin. Minimum inhibitor concentration (MIC) value of gentamicin-susceptible bacteria was determined as ≤ 2 μ g/ml in dogs, ≤ 4 μ g/ml in other species and gentamicin-resistant bacteria was 8 - 16 μ g/ml. It was reported that MIC value was in the range of 0.0025 - 0.0019 μ g/ml against S. intermedius isolates; MIC limits of gentamicin were detected as 2 μ g/ml \leq S (susceptible) and μ g/ml \leq R (resistant) for P. aeruginosa. Pharmacokinetic properties: Aminoglycosides, the polar compounds are poorly absorbed from the biological membranes and they don't distribute the tissues such as eye. Dropping of 1 or 2 drops to eye, provides the therapeutic levels longer than 6 hours. The possibility of systemic absorption is low. Gentamicin can not be detected in blood after administration of the recommended dose. Transdermal absorption is negligible level after administration to ear canal. **AREA OF USE/ INDICATIONS** Gentavet-G Eye and Ear Drops; is used in the treatment of blepharitis, conjunctivitis, keratoconjunctivitis (including post-operative keratitis), anterior uveitis treatment caused by the susceptible bacteria in cat, dog and rabbits and the treatment of acute outer ear infection in dogs. **ROUTE OF ADMINISTRATION AND DOSAGE:** It is administered to conjunctival sac in eye infections of cat, dog and rabbit and controlled within 5-7 days. Ocular examination should be done with frequent intervals during the long-term treatment. In order not to develop any response within 7-14 days to the evaluated again. Treatment period is 7 days in dog ear infections. After the administration, the base of the ear can be gently and shortly massaged so that the Long-term use of local antibiotics may cause growth of the organisms such as fungi. In this situation, antibiotic administration should be terminated and a proper **INFORMATION AND WARNING FOR TARGET SPECIES** Dropper tip should be cleaned after each administration. If both eye and ear administration are done to the to prevent infection transition. In the eye diseases; in vitro susceptibility tests should be done before the treatment, if possible. During the use, legal national and Ocular examination should be done with frequent intervals during the long-term treatment. In non-infectious ocular diseases such as uveitis or allergic conjunctivitis, it can be used in corneal erosion or superficial ulcer situations. In the ear infections; Outer ear canal should be examined in detail to ensure there is no perforation purpose is to avoid the risk of transmission of the infection to the middle ear and prevent the vestibular structures from damaging. Outer ear should be cleaned and around the area to be treated should be cut. The use of the product is recommended according to the susceptibility test of the bacteria isolated from the sick be based on local (regional, on farm level) epidemiological information related to susceptibility of the target bacteria. It is stated that the use of gentamicin ear in perforation. Improper use of the product according to the instructions may increase the prevalence of the gentamicin resistant bacteria or decrease efficacy of the treatment with other aminoglycosides due to the cross-resistance. If resistance has developed against gentamicin, cross-resistance is also seen in other aminoglycoside antibiotics of which it is a member. In case of no response is obtained from the treatment, microbiological culture and susceptibility tests should be repeated. It is known that gentamicin is related to ototoxicity when administered at higher doses by systemic route. It should be used carefully in neonates and geriatrics by adjusting the dosage. If the infection has developed as secondary, the real cause should be treated as first. In order not to develop of the infections in animals, routine health controls should be done by the veterinary physician. special precautions should be taken in order to provide animal wealth properly during the operations such as feeding, sheltering, transportation, milking etc. within the good animal husbandry practices. Use during pregnancy and lactation: Safety of use of the veterinary pharmaceutical product was not detected during pregnancy and lactation. It should be used after evaluating of the benefit/risk by the veterinary physician. **ADVERSE EFFECTS** Aminoglycosides may cause ototoxic effects resulting with tinnitus in inner ear organs, equilibrium and hearing loss. Long-term use may cause renal failure occurring with toxic effects on kidneys, but these effects disappear upon termination of treatment. Aminoglycosides may bind to post-synaptic receptors and cause neuromuscular blockage. Topical ophthalmic side effects of aminoglycosides are known including corneal injury, conjunctival injury and hypersensitivity reactions. Ocular burning and irritation, non-specific conjunctivitis, conjunctival epithelial defects and conjunctival hyperemia are the side effects frequently reported and allergic reactions, thrombocytopenic haemorrhages are other adverse effects rarely seen. Hypersensitivity and localized ocular toxicity (itching, swelling on the eye lid and conjunctival erythema) were reported rarely. It has been reported that mydriasis and conjunctival paresthesia may occur. It is stated that gentamicin may retard the healing of the corneal ulcers and may cause local irritations. **DRUG INTERACTIONS** Due to adverse effects of aminoglycosides, they should not be used concurrently with other aminoglycosides, neurotoxic, nephrotoxic, ototoxic treatments. Also they should not be used together with tetracyclines, sulfonamides which have harmful effects on kidney with other neuromuscular blockers, anaesthetics and nonsteroidal antiinflammatory drugs. Toxic effect increases on kidney and inner ear in case of using together with iron preparations, furosemide, amphotericin B, polymyxin B, vancomycin, cephalothin. Gentamicin should not be used with ampicillin sodium, furosemide, cephalothin sodium, heparin sodium and cephalapin sodium. **OVERDOSE (Symptoms, Precautions and Antidote)** In case of severe irritation occurs in the eye, the treatment should be terminated immediately. It may cause ototoxicity due to damage in the vestibular and cochlear parts of the auditory nerve when used for a long time and above the recommended dose. Treatment should be terminated as soon as signs of ataxia and incoordination appear in animals. **WITHDRAWAL PERIOD** should not be used in rabbits raised for human consumption. **CONTRAINDICATIONS** It should not be used in animals known to be susceptible to aminoglycosides. It should not be administered to dogs with perforated eardrum. It should not be used in cases of known hypersensitivity to any of its ingredients. **GENERAL WARNINGS** Consult a veterinarian before use or in case of an unexpected effect. Keep out of reach of children. **SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS** People who are known to be hypersensitive to gentamicin and/or aminoglycosides should avoid contact with the product. Due to the irritating property of the benzalkonium chloride in its composition it may cause irritation on skin and eye. Protective equipment should be used (gloves, mask, glasses etc.) during the treatment. Avoid of product contact with skin and eye. In case of contact, wash eye and skin with plenty of water. In case of swelling on face, eye and lips, difficulty in breath and tachycardia occurs after the administration, emergency medical intervention is necessary. In case of this situation, consult to doctor with the product and the leaflet. **STORAGE CONDITIONS AND SHELF LIFE** Shelf life is 36 months from the manufacturing date when stored at room temperature below 25°C, protecting from light, without refrigeration and freezing. The product should be stored at room temperature below 25°C protecting from light, without refrigeration and freezing and should be used in 28 days after the first opening. **NATURE AND COMPOSITION OF THE PACKAGING** It is presented in 5 ml, self-sealing dropper, white coloured, opaque polyethylene bottles covered with white coloured polyethylene cap with safety ring in a cardboard box with the leaflet. **TERMS OF SALE** Sold only in veterinary clinics and pharmacies by veterinary prescription. **MARKETING AUTHORIZATION DATE AND NO.** 26.09.1986/06/533 **NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER** DEVA Holding A.Ş. Halkalı Merkez Mahallesi Basın Ekspres Cad. No:1 Küçükçekmece/İstanbul/TURKEY **NAME AND ADDRESS OF THE MANUFACTURING SITE** DEVA Holding A.Ş. Dumlupınar Mah. Ankara Caddesi No:2 Kartepe/Kocaeli/TURKEY

Cat, Dog, Rabbit- Eye Drop Dosage	1-2 drops thrice a day (2x0.101-0.202 mg Gentamicin)
Dog-Ear Drop	Dogs less than 15 kg: 3 drops twice a day (3x1.01-0.303 mg Gentamicin) Dogs more than 15 kg: 6 drops twice a day (6x1.01-0.606 mg Gentamicin)
1 drop contains 0.101 mg gentamicin.	



Health
in each drop...



COMPOSITION

Each ml contains
Gentamicin Sulfate
 equivalent to
 3 mg Gentamicin base.






AREA OF USE/INDICATIONS

It is used in the treatment of **blepharitis, conjunctivitis, keratoconjunctivitis** (including post-operative keratitis), anterior uveitis treatment caused by the susceptible bacteria in **cat, dog and rabbits** and the treatment of acute outer ear infection in dogs.

PHARMACOLOGICAL PROPERTIES

- **Pharmacodynamic properties:** Gentamicin is a broad spectrum antibiotic and bactericidal. It is particularly effective against fast-growing organisms. Gentamicin acts by irreversibly binding to the 30S ribosomal subunit, thus protein synthesis is inhibited in susceptible bacteria. Gram-positive and Gram-negative bacteria including *Staphylococcus intermedius*, coagulase-positive *Staphylococcus* spp. and pathogenic organisms isolated from the ears of the dogs such as *Proteus mirabilis* are spectrum in activity.
- **Pharmacokinetic properties:** Aminoglycosides, the polar compounds are poorly absorbed from the biological membranes and they don't distribute the tissues such as eye. Dropping of 1 or 2 drops to eye, provides the therapeutic levels longer than 6 hours. The possibility of systemic absorption is low. Gentamicin can not be detected in blood after administration of the recommended dose. Transdermal absorption is negligible level after administration to ear canal.

ROUTE OF ADMINISTRATION AND DOSAGE

	Cat, Dog, Rabbit Eye Drop	1-2 drops thrice a day (2x0.101=0.202 mg Gentamicin)
	Dog Ear Drop	Dogs less than 15 kg: 3 drops twice a day (3x1.01=0.303 mg Gentamicin) Dogs more than 15 kg: 6 drops twice a day (6x1.01=0.606 mg Gentamicin)
		

💧 1 drop contains 0.101 mg gentamicin.

It is administered to conjunctival sac in eye infections of cat, dog and rabbit and controlled within 5-7 days. Ocular examination should be done with frequent intervals during the long-term treatment.

Treatment period is 7 days in dog ear infections. After the administration, the base of the ear can be gently and shortly massaged so that the preparation enters the lower part of the ear canal.

