

SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the veterinary medicinal product**

Clinagel-Vet, gentamicin 0.30% w/w eye gel

2. **Qualitative and quantitative composition**

<i>Active substance(s)</i>	<i>% w/w</i>
Gentamicin (as Gentamicin sulphate)	0.30

<i>Excipient(s)</i> Benzalkonium chloride	0.01
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For full list of excipients, see section 6.1.

3. **Pharmaceutical form**

Eye gel.
Clear, colourless, viscous gel.

4. **Clinical particulars**

4.1. ***Target species***

Dogs and cats.

4.2. ***Indications for use, specifying the target species***

Indicated for the treatment of infections of the external structures of the eyes and the eyelids caused by bacteria which are sensitive to gentamicin. These infections include bacterial conjunctivitis, keratitis and bacterial keratoconjunctivitis, ulcers and abscesses of the cornea, blepharitis and blepharconjunctivitis, acute meibomitis and dacryocystitis.

Treatment of infectious complications caused by foreign material in the cornea or conjunctiva and infections associated with traumata caused by a physical or chemical agent.

4.3. ***Contra-indications***

Hypersensitivity to one of the components of the product.

4.4. ***Special warnings for each target species***

For use under veterinary supervision only. In cases of long-term treatment, re-examination should be performed at intervals (see also 4.5).

- 4.5. i. *Special precautions for use in animals***
As is the case for other antibiotics, long term topical treatment can cause overgrowth of non-sensitive organisms such as fungi.
Avoid contact between the tube and the eye.
For external use only.
Do not use concurrently with other antimicrobial ophthalmic products.
Due to likely variability (time, geographical) in the occurrence of resistance of bacteria for Gentamicin sulphate, bacteriological sampling and susceptibility testing are recommended.
- ii. *Special precautions to be taken by the person administering the medicinal product to the animals***
People with known allergy (hypersensitivity) to aminoglycosides should avoid contact with this product.
Wash hands after use.
- 4.6. *Adverse reactions (frequency and seriousness)***
There are no reports about local intolerance. In case of allergic reaction it is recommended to stop the treatment.
Benzalkonium chloride can cause allergic reactions.
- 4.7. *Use during pregnancy, lactation or lay***
The product may be used during pregnancy, lactation or lay.
- 4.8. *Interaction with other medicinal products and other forms of interaction***
Incompatible with certain other antimicrobial compounds e.g. penicillins.
- 4.9. *Amounts to be administered and administration route***
Administer in small amounts (\pm 1 cm strip) two or three times a day, in the conjunctival cul-de-sac of the lower eye lid. The duration of the treatment is one to several weeks, depending on the nature and the gravity of the infection.
- 4.10. *Overdose (symptoms, emergency procedures, antidotes), if necessary***
Up to now no overdosing has been reported. Due to the product being presented in a small tube, intoxication due to accidental uptake is unlikely.
- 4.11. *Withdrawal periods***
Not applicable.
- 5. Pharmacological properties**
ATCvet Code: QS01AA11
Summary presentation of the active substance
Gentamicin is one of the most active aminoglycosides and has a high therapeutic activity against a number of Gram-positive and Gram-negative bacteria.
Gentamicin is a bactericidal antibiotic and acts by interfering with bacterial protein synthesis.

5.1. *Pharmacodynamic properties*

Gentamicin is bactericidal and acts by interfering with bacterial protein synthesis by binding irreversibly to the 30S subunit of the bacterial ribosome. The aminoglycosides also cause misreading that results in an incorrect amino acid being inserted into the protein chain. Gentamicin also causes termination of the protein chain too quickly or various other defects. One of all these factors results in the synthesis of defective proteins, causing death of the bacteria. Bacteria are more susceptible to the aminoglycosides when they are rapidly synthesizing proteins. As this whole process takes at least an hour or more to kill the bacteria, bactericidal tissue levels must be maintained for at least 2 hours to obtain the desired results (Clark, 1977c (13); de Visser; 1985 (15)). Other mechanisms of action may contribute to the bactericidal effect of gentamicin.

Gentamicin is active against Gram-positive bacteria such as coagulase-positive and coagulase-negative staphylococci, including some penicillin-resistant strains, group-A β -haemolytic and not-haemolytic streptococci. A number of streptococci are resistant to gentamicin. Gram-negative bacteria showing susceptibility include some *Pseudomonas* strains, indol-positive and indol-negative *Proteus* strains, *Campylobacter*, *Citrobacter*, *Escherichia coli*, *Aerobacter aerogenes*, *Moraxella lacunata*, *Neisseria*-strains, including *Neisseria gonorrhoeae*, *Enterobacter*, *Serratia*-group, *Acinetobacter*, *Providencia*, *Klebsiella* and *Pasteurella*.

5.2. *Pharmacokinetic properties*

Aminoglycosides are polar compounds poorly absorbed across biological membranes and not distributed into tissues such as the eye. Taking into account the low concentration of gentamicin in the product and the small amounts of gel administered, there is little chance for systemic resorption. No gentamicin could be detected in the blood after normal administration of the product.

6. Pharmaceutical particulars

6.1. *List of excipients*

Benzalkonium Chloride
Disodium Phosphate Dihydrate
Sodium Dihydrogen Phosphate Dihydrate
Sodium Chloride
Hypromellose
Water for injections

6.2. *Incompatibilities*

Gentamicin is incompatible with erythromycin, chloramphenicol, sodium sulfadiazine, sodium carbonate and frusemide.

6.3. *Shelf life*

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after opening the immediate packaging: 1 month.

- 6.4. *Special precautions for storage***
Do not store above 25 °C. Care should be taken to avoid contamination of content during use. Replace cap between applications.
Any contents remaining one month after the date on which the container was first opened should be discarded.
- 6.5. *Nature and composition of immediate packaging***
4g aluminium epoxy-phenol lacquered tube with membrane closure, white cap used to pierce seal and close tube after initial opening.
- 6.6. *Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate***
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
- 7. Marketing Authorisation Holder**
Ecuphar n.v./s.a.
Legeweg 157 –I
B-8020 Oostkamp
Belgium.
- 8. Marketing Authorisation Number**
Vm 32742/4000
- 9. Date of the first authorisation**
23 November 2001
- 10. Date of revision of the text**
26 November 2008