SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tiacil 0.50% w/v Eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)	**% w/v**
Gentamicin sulphate, (activity 600 IU/mg)……	0.50
Excipients	
Parahydroxybenzoic acid…….	0.09
Disodium Edetate……..	0.50

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye drops, solution.
Sterile, opalescent, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats, dogs and rabbits

4.2 Indications for use, specifying the target species

For the treatment of blepharitis, conjunctivitis, keratoconjunctivitis (including post- operative keratitis) and anterior uveitis, in dogs, cats and rabbits

4.3 Contraindications

Do not use in animals with known hypersensitivity to gentamicin or other aminoglycosides.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals
Official, national and regional antimicrobial policies should be taken into

account when the product is used.
Where possible, in vitro sensitivity tests should be undertaken prior to treatment.
Occular re-examination should be made at frequent intervals during prolonged therapy.
Tiacil Ophthalmic solution may be used in case of corneal erosion or superficial ulcer.

ii. Special precautions for the person administering the veterinary medicinal product to 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)

Rare cases of local intolerance (conjunctival inflammatory reactions) can be observed at the onset of treatment. In rare cases acute irritation and pain may occur. These reactions are transitory, and they disappear spontaneously without any specific treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

No special precautions.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

Apply 1 or 2 drops directly into the conjunctival sac three times a day until control is achieved, which in most cases can be expected after 5 to 7 days.

Care should be taken to avoid contamination of the contents during use. Ocular re-examination should be made at frequent intervals during extended therapy.
If there is no response to treatment withing 7 to 14 days or the condition worsens, the diagnosis should be re-established

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In cases of severe irritation, the treatment should be stopped immedately and the diagnosis reassessed.

4.11 Withdrawal period(s)

Not for use in rabbits intended for human consumption

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QS01AA11

Tiacil is an ophthalmic solution containing Gentamicin sulphate as active ingredient, an antibiotic of the aminoglycoside family.

5.1 Pharmacodynamic properties

Gentamicin is a broad spectrum bactericidal antibiotic, active against such organisms as *Klebsiella* and *Pseudomonas*. Gentamicin is particularly effective on rapidly multiplying organisms. Gentamycin is lethal to susceptible bacteria mainly by binding to bacterial ribosomes and impairing protein synthesis.

5.2 Pharmacokinetic particulars

The application of one or two drops to the eye enables the persistence of therapeutic levels for more than 6 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Parahydroxybenzoic
Acid Disodium Edetate
Hypromellose
Povidone K30
Sodium Chloride
Sodium Hydroxide (for pH adjustment) Trometamol
Water for injection

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2

years Shelf life after opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C
Any contents remaining 28 days after the date on which the container was first opened should be discarded.
Care should be taken to avoid contamination of the contents during use. Following withdrawal of first dose, use the product within 28 days.

6.5 Nature and composition of immediate packaging

5 ml type II amber glass bottles with blue polyethylene low density cap and blue rubber chlorobutyl dropper.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
6516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4026

9. DATE OF FIRST AUTHORISATION

29 January 1993

10. DATE OF REVISION OF THE TEXT

August 2023

Approved 30 August 2023