PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton box of 5 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tiacil 0.50% w/v Eye drops, solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

COMPOSITION

Active substance

Gentamicin as sulphate, (Potency 600 IU/mg): 0.50 **%** w/v

Excipients

Preservatives:
Parahydroxybenzoic acid 0.090
% w/v Disodium Edetate 0.50 **%**
w/v

3. PHARMACEUTICAL FORM

Eye drops, solution.
Sterile, opalescent, aqueous solution.
Sterile antibiotic eye drops for dogs, cats and rabbits

4. PACKAGE SIZE

Glass bottle with integral plastic dropper. 5ml vial.

5. TARGET SPECIES

Cats, dogs and rabbits.

6. INDICATIONS

For the treatment of blepharitis, conjunctivitis, keratoconjunctivitis (including post-operative keratitis) and anterior uveitis, in dogs, cats and rabbits.
May be used in case of corneal erosion or superficial ulcer.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

RECOMMENDED DOSE AND DOSAGE SCHEDULE

Apply 1 or 2 drops of TIACIL 0.50% w/v Eye drops, solution should be instilled 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 within 7 to 14 days or the condition worsens, the diagnosis should be re-established.

8. WITHDRAWAL PERIOD

Not for use in rabbits intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

GENERAL PRECAUTIONS
Keep out of reach of children. For animal treatment only.
Ocular re-examination should be made at frequent intervals during prolonged therapy.

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. Tiacil Ophthalmic solution may be used in case of corneal erosion or superficial ulcer.

USER WARNINGS
People with known allergy (hypersensitivity) to aminoglycosides should avoid contact with this product.
Wash hands after use.

UNDESIRABLE EFFECTS
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.

DISPOSAL ADVICE
Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

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

10. EXPIRY DATE

Exp.: xxxxxxx

11. SPECIAL STORAGE CONDITIONS

PHARMACEUTICALS WARNINGS
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.
Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF

For animal treatment only.
UK authorised veterinary medicinal product

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac
06516 Carros France

Distributed by VIRBAC Ltd. Suffolk IP30 9UP
UK

16. MARKETING AUTHORISATION NUMBER

Vm 05653/4026

Once opened, used by: **.....**

17. MANUFACTURER'S BATCH NUMBER

Lot: xxxxx

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Label of 5 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tiacil 0.50% w/v Eye drops, solution

Sterile antibiotic eye drops for dogs, cats and rabbits.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

COMPOSITION
Gentamicin sulphate, (potency 600 IU/mg): - 0.50 % w/v
Preservatives: - Parahydroxybenzoic acid 0.090 **%** w/v - Disodium edetate 0.50 **%** w/v.
See package leaflet for directions of use & user warnings. Not for use in rabbits intended for human consumption.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml

4. ROUTE(S) OF ADMINISTRATION

Eye drops solution

5. WITHDRAWAL PERIOD

Not for use in rabbits intended for human consumption.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

Vm 05653/4026

POM-V

UK authorised veterinary medicinal product. To be supplied only on veterinary prescription. Do not store above 25°C. Wash hands after use.
For animal treatment only. Keep out of reach of children.

M.A.H.: Virbac - 06516 Carros – France
Distributed by VIRBAC Ltd. - Suffolk IP30 9UP – UK

PACKAGE LEAFLET FOR:

Sterile antibiotic eye drops for dogs, cats and rabbits.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tiacil 0.50% w/v Eye drops, solution

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

COMPOSITION

Active substance(s)

Gentamicin sulphate, (potency 600 IU/mg)……

Excipients

As preservative:
Parahydroxybenzoic acid (90 mg)…….
Disodium Edetate (500 mg)……..
0.50 % w/v
0.09 % w/v
0.50 % w/v

PROPERTIES
TIACIL 0.50% w/v Eye drops, solution is sterile and isotonic, characterised by its special long acting formulation, this reducing the number of daily applications. After administration, TIACIL 0.50% w/v Eye drops, solution covers the cornea and provides for the maintenance of therapeutic levels of the antibiotic for no less than 6 hours. Gentamicin is a bacterial antibiotic active against most gram positive and gram negative bacteria responsible for ocular infections. TIACIL 0.50% w/v Eye drops, solution may be used in cases of corneal erosion or superficial ulcer.

4. INDICATIONS

For the treatment of blepharitis, conjunctivitis, keratoconjunctivitis (including post-operative keratitis) and anterior uveitis, in dogs, cats and rabbits.
Official, national and regional antimicrobial policies should be taken into account when the product is used.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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).

7. TARGET SPECIES

Cats, dogs and rabbits.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

RECOMMENDED DOSE AND DOSAGE SCHEDULE
1 or 2 drops of TIACIL 0.50% w/v Eye drops, solution should be instilled 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.
If there is no response to treatment within 7 to 14 days or the condition worsens, the diagnosis should be re-established.

- Where possible, in vitro sensitivity tests should be undertaken prior to treatment.
- Ocular re-examination should be made at frequent intervals during extended therapy.

9. ADVICE ON CORRECT ADMINISTRATION

None.

UNDESIRABLE EFFECTS
In rare cases, acute irritation and pain may occur. This resolves spontaneously.

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

10. WITHDRAWAL PERIODS

Not for use in rabbits intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL WARNINGS
Do not store above 25°C.
Following withdrawal of first dose, use the product within 28 days.
When the container is opened for the first time, the discard date should be defined as being 28 days after the date on which the container was first opened. The discard date should be written in the space provided on the outer carton.
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.
Keep the container in the outer carton.

12. SPECIAL USER WARNINGS

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. Ocular 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.

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.
In rare cases, acute irritation and pain may occur. This resolves spontaneously.
In cases of severe irritation, the treatment should be stopped immediately and the diagnosis reassessed.

Use during pregnancy or lactation
No special precautions.

Interaction with other medicinal products and other forms of interaction
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

DISPOSAL ADVICE
Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2023

PRESENTATION
5ml glass bottle with integral plastic dropper

15. OTHER INFORMATION

UK authorised veterinary medicinal product.

POM-V

To be supplied only on veterinary prescription.

Vm 05653/4026

For animal treatment only. Keep out of reach of children.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
Virbac - 1ère Avenue, 2065 m – LID - 06516 Carros - France

Distributed by
VIRBAC Limited. – Windmill Avenue - Woolpit Business park - Woolpit – Bury St Edmunds - Suffolk IP30 9UP – United Kingdom

Manufacturer responsible for batch release:
LABIANA LIFE SCIENCES, S.A
C/ Venus, 26, Pol. Ind. Can Parellada TERRASSA 08228 BARCELONA
SPAIN

Approved 30 August 2023