LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE

Outside of tear-open leaflet
{ 50 ml, 150 ml, 200 ml, 300 ml, 400 ml }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAF Spray 28.5 mg/g Cutaneous spray, solution
Thiamphenicol

2. STATEMENT OF ACTIVE SUBSTANCE

Each g contains:
Active substance:
Thiamphenicol 28.5 mg

3. PHARMACEUTICAL FORM

Cutaneous spray, solution.

4. PACKAGE SIZE

50, 150 ml, 200 ml, 300 ml, 400 ml

5. TARGET SPECIES

Horses, cattle, goats, sheep, pigs, mink, rabbits

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal:
- horses, cattle, goats, sheep, rabbits: zero days.
- pigs: 14 days.

Milk: 0 hours
Do not use on the udder of lactating animals if their milk is intended for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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

For animal treatment only. 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

Eurovet Animal Health BV, Handelsweg 25, 5531 AE Bladel, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4051

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

Warning sentences should be kept together; no need for boxed area

Extremely flammable aerosol. Pressurized container: May burst if heated.
Protect from sunlight. Do not expose to temperatures exceeding 50°C.
Keep away from heat/hot surfaces/sparks/ open flames and other ignition sources.
No smoking.
Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.

Danger

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

{150 ml, 200 ml, 300 ml, 400 ml}

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder:
Eurovet Animal Health BV, Handelsweg 25, 5531 AE Bladel, The Netherlands

Manufacturer for batch release:
Eurovet Animal Health BV, Handelsweg 25, 5531 AE Bladel, The Netherlands
IGS Aerosols GmbH, Im Hemmet 1 und 2, 79664 Wehr, Germany

2. Name of the veterinary medicinal product

TAF Spray 28.5 mg/g Cutaneous spray, solution
Thiamphenicol

3. Statement of the active substance and other ingredients

Each g contains:
Active substance:
Thiamphenicol 28.5 mg
Excipient:
Curcumine (E100) 0.5 mg

4. Pharmaceutical form

Cutaneous spray, solution.
Clear yellow solution.

5. Package size

150 ml, 200 ml, 300 ml, 400 ml

6. Indications

In all target species:
- Treatment of superficial wound infections caused by micro-organisms susceptible to thiamphenicol.

In cattle, goats and sheep:
- Treatment of infections of the claw and hoof such as foot rot, interdigital dermatitis, digital dermatitis caused by micro-organisms susceptible to thiamphenicol.

7. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. See also section 'Withdrawal period'.

8. Adverse reactions

None known.
If you notice any side effects, even those not already listed on this label or you think that the medicine has not worked, please inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}.

9. Target species

Horses, cattle, goats, sheep, pigs, mink, rabbits.

10. Dosage for each species, route and method of administration

Cutaneous use.
Spray the solution on the affected area for 3 seconds (equivalent to approximately 45 mg thiamphenicol) once a day. Treatment can be repeated depending on the healing process, up to 3 consecutive days.

11. Advice on correct administration

Shake the container thoroughly before spraying. The container should be held at a distance of approximately 15-20 cm from the area to be sprayed. For optimal use, wounds should be cleaned before application. The spray container is suitable to be used in upright and inverted positions.

12. Withdrawal periods

Meat and offal:
- horses, cattle, goats, sheep, rabbits: zero days.
- pigs: 14 days.

Milk: 0 hours
Do not use on the udder of lactating animals if their milk is intended for human consumption.

13. Special storage precautions

Do not use this veterinary medicinal product after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

14. Special warnings

Special warnings for each target species
Clean the affected area thoroughly before spraying. After administration of the product the animal should be kept on dry ground for at least one hour.

Special precautions for use in animals
Protect the eyes when spraying in the vicinity of the head. The animal should be prevented from licking the treated area, or treated areas on other animals. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. Use of the product deviating from the instructions given on this label may increase the prevalence of bacterial resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In cases of accidental eye contact, this product may cause irritation. The use of eye protection (such as safety glasses) is recommended. Do not spray towards a person. If irritation occurs, seek medical advice and show the label to the physician.

Asthma and rhinitis may occur following inhalation. Do not inhale vapours. Apply the product in the open air, or in a sufficiently ventilated area.

This product can be toxic when ingested.
Contact with the treated area should be avoided and children should not be allowed to play with treated pet animals until the application site is dry.
Do not eat, drink or smoke during administration.

Hypersensitivity (allergy) to thiamphenicol may occur rarely. People with known hypersensitivity to thiamphenicol should avoid contact with the veterinary medicinal product. Should symptoms occur such as swelling of the face, lips or eyes or difficulty in breathing, seek urgent medical attention.

Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

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

Overdose (symptoms, emergency procedures, antidotes):
None known.

Incompatibilities:
None known.

15. Special precautions for the disposal of unused product or waste materials

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

16. Date on which the label was last approved

November 2021

17. Other information

Pack sizes: 50, 150, 200, 300 and 400 ml
Not all pack sizes may be marketed.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

21. Marketing authorisation number(s)

Vm 16849/4051

22. Manufacturer's batch number

Batch: {number}

Warning sentences should be kept together; no need for boxed area

Extremely flammable aerosol. Pressurized container: May burst if heated.
Protect from sunlight. Do not expose to temperatures exceeding 50°C.
Keep away from heat/hot surfaces/sparks/ open flames and other ignition sources.
No smoking.
Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.

Danger

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
TAF Spray 28.5 mg/g Cutaneous spray, solution

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

Marketing authorisation holder:
Eurovet Animal Health BV, Handelsweg 25, 5531 AE Bladel, The Netherlands

Manufacturer for batch release:
Eurovet Animal Health BV, Handelsweg 25, 5531 AE Bladel, The Netherlands
IGS Aerosols GmbH, Im Hemmet 1 und 2, 79664 Wehr, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAF Spray 28.5 mg/g Cutaneous spray, solution
Thiamphenicol

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

1 g contains
Active substance:

Thiamphenicol	28.5 mg

Excipient:

Curcumine (E100)	0.5 mg

Cutaneous spray, solution.
Clear yellow solution.

4. INDICATIONS

In all target species:
- Treatment of superficial wound infections caused by micro-organisms susceptible to thiamphenicol.

In cattle, goats and sheep:
- Treatment of infections of the claw and hoof such as foot rot, interdigital dermatitis, digital dermatitis caused by micro-organisms susceptible to thiamphenicol.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. See also section ‘Withdrawal period’.

6. ADVERSE REACTIONS

None known.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Horses, cattle, goats, sheep, pigs, mink, rabbits.

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

Cutaneous use.
Spray the solution on the affected area for 3 seconds (equivalent to approximately 45 mg thiamphenicol) once a day. Treatment can be repeated depending on the healing process up to 3 consecutive days.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the container thoroughly before spraying. The container should be held at a distance of approximately 15-20 cm from the area to be sprayed. For optimal use, wounds should be cleaned before application. The spray container is suitable to be used in upright and inverted position.

10. WITHDRAWAL PERIOD

Meat and offal:
- horses, cattle, goats, sheep, rabbits: zero days.
- pigs: 14 days.

Milk: 0 hours.
Do not use on the udder of lactating animals if their milk is intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Extremely flammable aerosol. Pressurised container: May burst if heated.
Protect from sunlight. Do not expose to temperatures exceeding 50°C.
Keep away from heat/hot surfaces/sparks/open flames and other ignition sources. No smoking.
Do not use this veterinary medicinal product after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species
Clean the affected area thoroughly before spraying. After administration of the product the animal should be kept on dry ground for at least one hour.

Special precautions for use in animals
Protect the eyes when spraying in the vicinity of the head. The animal should be prevented from licking the treated area, or treated areas on other animals. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. Use of the product deviating from the instructions given in this leaflet may increase the prevalence of bacterial resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In cases of accidental eye contact, this product may cause irritation. The use of eye protection (such as safety glasses) is recommended. Do not spray towards a person. If irritation occurs, seek medical advice and show the package leaflet to the physician.

Asthma and rhinitis may occur following inhalation. Do not inhale vapours. Apply the product in the open air, or in a sufficiently ventilated area.

This product can be toxic when ingested.
Contact with the treated area should be avoided and children should not be allowed to play with treated pet animals until the application site is dry.
Do not eat, drink or smoke during administration.

Hypersensitivity (allergy) to thiamphenicol may occur rarely. People with known hypersensitivity to thiamphenicol should avoid contact with the veterinary medicinal product. Should symptoms occur such as swelling of the face, lips or eyes or difficulty in breathing, seek urgent medical attention.

Wash hands after use.

Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

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

Overdose (symptoms, emergency procedures, antidotes):
None known.

Incompatibilities:
None known.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

15. OTHER INFORMATION

Pack sizes: 50, 150, 200, 300 and 400 ml
Not all pack sizes may be marketed.
For animal treatment only. To be supplied only on veterinary prescription.

Approved 26 November 2021