

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animedazon Spray, 2.45 % w/w cutaneous spray suspension for cattle, sheep and pigs

Chlortetracycline hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each spray container contains:

Active substance:

Chlortetracycline hydrochloride 3.210 g (equivalent to 2.45 % w/w)
(equivalent to chlortetracycline 2.983 g)

Excipient(s):

Patent Blue V 85 % (E 131):	0.23 g
Isobutane (Propellant)	92.2 g

3. PHARMACEUTICAL FORM

Cutaneous Spray, Suspension

4. PACKAGE SIZE

211 ml

12 x 211 ml

5. TARGET SPECIES

Cattle, sheep, pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For cutaneous use.

Spray for 3 seconds until the treatment-area is evenly coloured, distance of approx..15-20 cm from the area to be sprayed.

Claw infections: repeat after 30 seconds.

Foot rot and foul in the foot: spray with a 30 second interval 1x or 2x daily. Repeat within 1 to 3 days depending on the seriousness of the injury and the rate of improvement treatment.

Superficial wounds: single administration, if contaminated with chlortetracycline sensitive agents.

Dermatitis digitalis: spray 2x with a 30 second interval for 3 consecutive days 1x or 2x daily.

Shake the container thoroughly before spraying.

8. WITHDRAWAL PERIOD

Meat and offal, milk: Zero days

Do not use on the udder of lactating animals if milk is intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

This product can cause serious eye irritation. Protect the eyes and face. Wear impermeable gloves.

Avoid breathing spray. Use only outdoors or in a well ventilated area. In case of accidental contact with the eyes or ingestion seek immediately medical advice and have the container on hand.

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.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate or freeze.

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

Disposal: read package leaflet

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 REACH AND SIGHT OF CHILDREN”

Keep out of the sight and reach of children
Danger



Sign for “Extremely flammable”.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4002

17. MANUFACTURER’S BATCH NUMBER

<Batch> <Lot> <BN> number

PACKAGE LEAFLET

Animedazon Spray, 2.45 % w/w cutaneous spray suspension for cattle, sheep and pigs

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

Marketing authorisation holder and manufacturer responsible for batch release:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animedazon Spray, 2.45 % w/w cutaneous spray suspension for cattle, sheep and pigs

Chlortetracycline hydrochloride

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

Each spray container contains:

Active substance:

Chlortetracycline hydrochloride 3.210 g (equivalent to 2.45 % w/w)
(equivalent to chlortetracycline 2.983 g)

Excipient(s):

Patent Blue V 85 % (E 131):	0.23 g
Isobutane (Propellant)	92.2 g

Evenly blue coloured spray

4. INDICATION(S)

Treatment of superficial traumatic or surgical wounds contaminated with chlortetracycline-sensitive agents. The product can be used as part of a treatment for superficial skin and claw infections, in particular interdigital dermatitis (foot rot and foul in the foot) and digital dermatitis caused by micro-organisms sensitive to chlortetracycline.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to tetracyclines. Do not use in cases of known resistance to tetracyclines.

6. ADVERSE REACTIONS

Hypersensitivity reactions may occur rarely.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep and pigs.

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

For cutaneous use. 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; spray for 3 seconds until the treatment-area is evenly coloured. In case of claw infections this treatment should be repeated after 30 seconds. For treatment of superficial wounds contaminated with chlortetracycline sensitive agents a single administration is recommended. For the treatment of dermatitis digitalis two administrations with a 30 second interval for 3 consecutive days once or twice daily is recommended. For treatment of other claw infections (foot rot and foul in the foot), two administrations with a 30 second interval once or twice daily is recommended. Depending on the seriousness of the injury and the rate of improvement treatment should be repeated within 1 to 3 days.

9. ADVICE ON CORRECT ADMINISTRATION

Please refer to section 8. "Dosage for each species, Routes and method of administration".

10. WITHDRAWAL PERIOD

Meat and offal: zero days

Milk: zero days

Do not use on the udder of lactating animals if milk is intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the container / the carton label after EXP.

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.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Protect the eyes of the animal when spraying in the vicinity of the head. Clean the affected area thoroughly before spraying. Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies. The animal should be discouraged from licking the treated area, or treated areas on other animals. After administration to the claw the animal should be kept on dry ground for at least one hour.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions to chlortetracycline. Wear appropriate impermeable gloves whilst handling the product. This product can cause serious eye irritation. Protect the eyes and face. If contact with the skin or eyes occurs, wash area immediately with clean fresh water. If irritation persists seek medical attention. Avoid inhaling vapours.

Apply the product in the open air or in well ventilated area. In case of accidental ingestion seek medical advice immediately and show the label to the physician. If contact with the skin or eyes occurs, wash area immediately with clean fresh water. If irritation persists seek medical attention. Wash hands after use.

Please refer also to section 11. "Special storage precautions".

Use during pregnancy and lactation

After cutaneous administration of Animedazon Spray, absorption of chlortetracycline is negligible. Therefore, Animedazon Spray is safe during pregnancy and lactation.

Pregnancy:

Can be used during pregnancy.

Lactation:

Please refer to section 10 "Withdrawal period(s)".

Other precautions

Stained part of the pigskin must be removed prior to the rest of the animal being used for human consumption.

Interaction with other medicinal products and other forms of interaction

After cutaneous administration of chlortetracycline spray, absorption of chlortetracycline is negligible. No data on interactions with other treatments are available. No interactions are expected.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION


1 spray container

Cardboard box with 12 x 1 spray container

The product is filled to 211 ml in a pressurised container of uncoated tin plate with a plastic valve mechanism and spraying nozzle.

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

 01 August 2016