ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

{Cardbox, Spray Container}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animedazon Spray, 2.45 % w/w cutaneous spray, suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each spray container contains:

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

3. PACKAGE SIZE

211 ml
12 x 211 ml

4. TARGET SPECIES

Cattle, sheep, pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

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 2x with a 30 second interval 1x or 2x daily. Repeat within 1 to 3 days depending on the seriousness of the injury and the healing progress.
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.

This veterinary medicinal 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.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal, milk: Zero days

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Extremely flammable aerosol. Pressurized container: May burst if heated.
Protect from direct 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. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.
Danger


Sign for "Extremely flammable".

13. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 24745/3001

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

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

3. Target species

Cattle, sheep, pigs

4. Indications for use

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

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use in cases of known resistance to tetracyclines.

6. Special warnings

Special precautions for safe use in the target species:
Protect the eyes of the animal when spraying in the vicinity of the head. Clean the affected area thoroughly before spraying. Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogen(s) at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional 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 veterinary medicinal product. This veterinary medicinal 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 veterinary medicinal product in the open air or in well-ventilated area. Do not eat or smoke whilst administering the veterinary medicinal product. Wash hands after use.
In case of accidental ingestion, seek medical advice immediately and show the label to the physician. Please refer also to section “Special storage precautions”.

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

Pregnancy:
Can be used during pregnancy.

Lactation:
Please refer to section “Withdrawal periods”.

Pregnancy and lactation:
After cutaneous administration of the veterinary medicinal product, absorption of chlortetracycline is negligible. Therefore, the veterinary medicinal product is safe during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
No data available. After cutaneous administration of chlortetracycline spray, absorption of chlortetracycline is negligible. Therefore, no interactions are expected.

7. Adverse events

Cattle, sheep, pigs:

Rare (1 to 10 animals / 10,000 animals treated):
Hypersensitivity reaction

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder < or its local representative > using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes 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 are 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 are recommended. Depending on the seriousness of the injury and the healing progress, treatment should be repeated within 1 to 3 days.

9. Advice on correct administration

Please refer to section “Dosage for each species, routes and method of administration”.

10. Withdrawal periods

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 this veterinary medicinal product after the expiry date which is stated on the container / the carton after Exp.
The expiry date refers to the last day of that month.

Extremely flammable aerosol. Pressurized container: May burst if heated.
Protect from direct 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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with

any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 24745/3001

Pack sizes:
1 spray container (211 ml)
Cardboard box with 12 x 1 spray container (211 ml)

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany
Tel: +49-2536-3302-0

Local representatives and contact details to report suspected adverse reactions:
FORTE Healthcare Limited,
Block 3, Unit 9,
CityNorth Business Campus,
Stamullen, Co.
Meath. K32 D990
Republic of Ireland
Tel.: +353 1 841 7666
E-Mail: pharmacovigilance@fortehealthcare.com

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Approved 14 May 2024