1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each spray container contains:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Patent Blue V 85 % (E 131)	0.23 g
Isobutane (Propellant)	92.2 g
Isopropyl alcohol	
Sorbitan trioleate	
Silica colloidal anhydrous	

Evenly blue coloured spray

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, pigs

3.2 Indications for use for each target species

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.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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 5.3 “Special precautions for storage”.

Special precautions for the protection of the environment:
Not applicable.

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

3.6 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. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative, or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

Pregnancy:
Can be used during pregnancy.

Lactation:
Please refer to section 3.12 “Withdrawal periods”.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QD06AA02

4.2 Pharmacodynamics

In vitro, chlortetracycline is primarily bacteriostatic. Chlortetracycline exerts its action by inhibiting the protein synthesis of the bacterial cell. In particular, cell division and the formation of the cell wall are impaired. Chlortetracycline binds to receptors on the 30S-subunit of the bacterial ribosome where they interfere with the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex.

4.3 Pharmacokinetics

After cutaneous administration of chlortetracycline spray, absorption of chlortetracycline is negligible. Therefore, the veterinary medicinal product will only have a local effect, no systemic effects are to be anticipated.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

1 spray container
Cardboard box with 12 x 1 spray container
The veterinary medicinal 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10826/005/001

8. DATE OF FIRST AUTHORISATION

24 October 2008

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

22 January 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).