SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animedazon Spray, 2.45 % w/w cutaneous spray suspension for cattle, sheep and pigs (AT, BE, BG, CZ, CY, DE, DK, EL, ES, FR, HR, HU, IE, IT, NL, PL, PT, RO, UK)
Animedazon, 2.45 % w/w cutaneous spray, suspension for cattle, sheep and pigs (EE, LT, LV, SI)
Animed vet, 2.45 % w/w cutaneous spray, suspension for cattle, sheep and pigs (IS, NO, SE)

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)

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cutaneous Spray, Suspension
Evenly blue coloured spray

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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

4.4 Special warnings

None.

4.5 Special precautions for use

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. Do not eat or smoke whilst administering the product. Wash hands after use.
Please refer also to section 6.4 “Special precautions for storage”.

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

4.6 Adverse reactions (frequency and seriousness)
Hypersensitivity reactions may occur rarely.

4.7 Use during 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.

Pregnancy:
Can be used during pregnancy.

Lactation:
Please refer to section 4.11 “Withdrawal period(s)”.

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

4.9 Amounts to be administered and administration route
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
Not applicable.

4.11 Withdrawal period(s)
Meat and offal: zero days
Milk: zero days

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibiotics for topical use, tetracycline and derivates
ATCvet code: QD06AA02

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Patent Blue V 85 % (E 131)
Isobutane
Isopropyl alcohol
Sorbitan trioleate
Silica colloidal anhydrous

6.2 Incompatibilities

None known.

6.3 Shelf life

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

6.4. 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 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.

6.5 Nature and composition of immediate packaging

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.

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

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

7. MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}>

10 DATE OF REVISION OF THE TEXT

{MM/YYYY} or <month YYYY>