SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Utertab 2000 mg intrauterine tablet for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each intrauterine tablet contains:
Active substance:
Tetracycline hydrochloride 2000.0 mg
(equivalent to 1848.2 mg tetracycline)

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intrauterine tablet
Yellow tablet with central score. The score line is not intended to divide the tablet into equal doses.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (lactating cow).

4.2 Indications for use, specifying the target species

For treatment and prevention of post parturient disorders in cattle: for administration following retained foetal membranes and endometritis caused by pathogens susceptible to tetracycline as well as after severe obstetrical procedures (fetotomy, caesarean section).

4.3 Contraindications

Do not use in infections caused by pathogens resistant to tetracycline.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in severe kidney or liver disorders.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Whenever possible, the product should only be used based on susceptibility testing. Official, national and regional antimicrobial policies should be taken into account when the product is used. Milk from treated cows should not be fed to calves up to the end of the milk withdrawal period, except during the colostral phase, due to potential for selection of resistance in intestinal flora of calves.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause sensitisation. Avoid direct contact with the skin or the mucous membranes.
Gloves should be worn when handling the veterinary medicinal product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Occurrence of renal disorders is enhanced in dehydrated animals.
Tetracycline can cause damage to the liver.
Photodermatitis often occurs in areas of sparsely pigmented skin if these are exposed to intensive sunlight.
Allergic reactions are rare.
In case of allergic or anaphylactic reactions, discontinue treatment immediately. Allergic reactions can be treated parenterally with glucocorticoids and antihistamines.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The product is specifically for use in the post-parturition period.

4.8 Interaction with other medicinal products and other forms of interaction

There is a potential antagonism between tetracyclines and antibiotics with bactericidal action.

4.9 Amounts to be administered and administration route

Intrauterine use.

Cows:
2 g tetracycline hydrochloride / cow / day
equivalent to 1 tablet / cow /day

Treat one to three times at intervals of 1 up to 2 days.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdose is not expected because each tablet represents a single dose. Please refer to section 4.6.

4.11 Withdrawal period(s)

Cattle:	Meat and offal	10 days
	Milk	96 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives and antiseptics for intrauterine use, antibacterials, tetracycline.
ATCvet code: QG51AA02.

5.1 Pharmacodynamic properties

Tetracycline (TC) is a broad spectrum antibiotic with bacteriostatic action *in vivo*. It acts by inhibiting protein synthesis at the ribosomal level, predominantly by binding to the 30S ribosomal subunits of bacteria. The spectrum includes Gram-positive and Gram-negative, aerobic and anaerobic pathogens.
Five mechanisms of resistance, of which the first and second are most common, have been described:
(1) Energy dependent efflux systems; (2) Ribosomal protection proteins dissociating tetracyclines from their binding site near the ribosomal AA-tRNA docking site; (3) Reduced uptake of tetracyclin, due to stress-induced down-regulation of the porins through which the drug crosses the outer cell wall of the gram-negative bacteria (4) Enzymatic inactivation- hydroxylation of carbon-11a, which disrupts the tetracyclines' β-keto-enol involved in ribosome binding; (5) Ribosomal 16S RNA mutation at the primary binding site of tetracyclines. Different tetracycline resistance (tet) genes have been characterized, whereby majority of known tet genes code for efflux pumps, some of the tet genes code for ribosomal protection proteins. Tetracycline resistance is usually acquired by means of plasmids or other mobile elements (e.g. conjugative transposons).

There is usually complete cross-resistance between tetracyclines.
For systemic action against most susceptible microorganisms, *in vivo* serum concentrations of 0.5 – 2 µg/ml are considered efficacious, which need to be sustained over a sufficiently long period of time. Concentrations of more than 2 µg/ml of tetracycline are easily obtained in lochia following intrauterine administration of the recommended dose.

5.2 Pharmacokinetic particulars

Absorption via mucous membranes is limited due to the amphotheric character of the molecule. Tetracycline is distributed unequally in the organism. The highest concentrations are reached in liver and kidney. Tetracycline is stored in calcifying tissues.
Tetracycline undergoes enterohepatic circulation and its antimicrobially active form is eliminated mainly via urine, faeces and milk. The biological half-life varies depending

on the route of administration; it is prolonged in neonates and animals with renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, microcrystalline
Maize starch
Starch, pregelatinised
Povidone K25
Silica colloidal anhydrous
Magnesium stearate

6.2 Major Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

White opaque PVC-PE-PVdC blister sealed with Aluminium foil containing 5 tablets.
Pack sizes:
Cardboard box of 2, 4, 10, 20, 40, 60, 80, 100 blisters of 5 intrauterine tablets.
Corresponding to pack sizes of 10, 20, 50, 100, 200, 300, 400 and 500 intrauterine tablets.
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

Vm 24745/4025

9. DATE OF FIRST AUTHORISATION

21 August 2018

10. DATE OF REVISION OF THE TEXT

August 2018

PROHIBITION OF SALE, SUPPLY AND/OR USE
To be supplied only on veterinary prescription.

Approved: 21 August 2018