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 mg
(equivalent to 1848.2 mg tetracycline)

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, microcrystalline
Maize starch
Starch, pregelatinized
Povidone K25
Silica colloidal anhydrous
Magnesium stearate

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle (lactating cows).

3.2 Indications for use for each 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).

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing. Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal 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 veterinary medicinal product may cause sensitisation.

People with a known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.

Avoid direct contact with the skin or the mucous membranes.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (lactating cows):

Rare (1 to 10 animals / 10 000 animals treated):	Allergic reactions
Undetermined frequency (cannot be estimated from the available data):	Photodermatitis[1] Renal disorders[2] Liver damage

[1] Often occurs in areas of sparsely pigmented skin if these are exposed to intensive sunlight.
[2] Enhanced in dehydrated animals.

In case of allergic or anaphylactic reactions, discontinue treatment immediately. Allergic reactions can be treated parenterally with glucocorticoids and antihistamines.

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

Pregnancy and lactation:

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

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

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.

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

Overdose is not expected because each tablet represents a single dose. Please refer to section 3.6.

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

Cattle:	Meat and offal	10 days.
	Milk	96 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :
QG51AA02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 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.

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)

VPA10826/024/001

8. DATE OF FIRST AUTHORISATION

17/08/2018

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

28/04/2026

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).