ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Utertab 2000 mg intrauterine tablet for cattle
Tetracycline hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Intrauterine tablet

4. PACKAGE SIZE

10, 20, 50, 100, 200, 300, 400 or 500 tablets

5. TARGET SPECIES

Cattle (lactating cow)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intrauterine use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:	Meat and offal	10 days
	Milk	96 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 24745/4025

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Utertab 2000 mg intrauterine tablet for cattle
Tetracycline hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

<Batch><Lot> {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Utertab 2000 mg intrauterine tablet for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Utertab 2000 mg intrauterine tablet for cattle
Tetracycline hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

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

4. INDICATION(S)

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).

5. 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.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (lactating cow)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Cattle:	Meat and offal	10 days
	Milk	96 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after {abbreviation used for expiry date}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

Use during pregnancy, lactation or lay
The product is specifically for use in the post-parturition period.

Interaction with other medicinal products and other forms of interaction:
There is a potential antagonism between tetracyclines and antibiotics with bactericidal action.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Overdose is not expected because each tablet represents a single dose. Please refer to section “Adverse reactions”.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

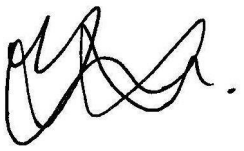
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

To be supplied only on veterinary prescription.



Approved: 12 December 2022