SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovocycline Pessary 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, oblong-shaped tablet, scored on one side. The tablet is not divisible.

4 CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

For treatment and prevention of post parturient disorders in cattle: for administration following dystocia, retained fetal membranes and endometritis caused by pathogens susceptible to tetracycline.

4.3 Contraindications

Do not use in infections caused by pathogens resistant to tetracycline.
Do not use in severe kidney and liver disorders.
Do not use in case of hypersensitivity to tetracyclines or to any of the excipients.

4.4 Special warning for each target species.

None.

4.5 Special precautions for use

Special precautions for use in animals

The product should be used based on susceptibility testing and take into account official, national and regional antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Direct contact with the skin or the mucous membranes of the user should be avoided. The use of gloves is recommended when administering the product to avoid sensitisation. Wash your hands after handling the product.

4.6 Adverse reactions (frequency and seriousness)

Long-term therapy requires careful monitoring to avoid super-infection (for example with yeasts).
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 sunlight.
Allergic reactions are rare. In case of allergic or anaphylactic reactions, discontinue treatment immediately. Allergic reactions can be treated parenterally with steroids and antihistamins.

4.7 Use during pregnancy, lactation or lay

The product is not indicated for use during pregnancy but can be used during lactation.

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

Tablet for intrauterine use.

Cows:
A dose of 2 g tetracycline hydrochloride per treatment, equivalent to 1 tablet per cow, is to be administered every 24 to 48 hours. The number of treatments required ranges from 1 to 3.
The tablet should not be divided.
It is recommended to remove part of the lochia by rectal massage before treatment. Before administration, the vulva and perineal area should be carefully washed and disinfected with a non-irritating solution and dried with disposable paper.
Treatment should be accompanied by an improvement in conditions of animal husbandry.

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

Please refer to section 4.6 “adverse reactions”.

4.11 Withdrawal periods

Cattle:	Meat and offal	10 days
	milk	4 days

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives and antiseptics for intrauterine use, antibiotics, tetracycline
ATC vetcode: QG51AA02

5.1 Pharmacodynamic properties

Tetracycline (TC) is a broad spectrum antibiotic with bacteriostatic action in vivo. The spectrum includes gram-positive and gram-negative, aerobic and anaerobic microorganisms. The primary pathogens involved in puerperal intrauterine infections, *Arcanobacterium (Actinomyces) pyogenes* and *Escherichia coli,* are susceptible to tetracycline. 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.
There is usually complete cross resistance amongst tetracyclines.

5.2 Pharmacokinetic particulars

Absorption via mucous membranes is limited due to the amphotheric properties of the molecule. Absorption of tetracycline hydrochloride from the uterus to the peripheral blood is limited in post parturient cows. The rate of absorption of tetracycline depends on various individual factors such as the relative blood flow to the myometrium, contractions of the uterus, lochial volume, discharge from the vulva and the severity of inflammation and infection. Tetracycline undergoes enterohepatic circulation and its antimicrobially active form is eliminated primarily via urine, faeces and milk. The biological half-life following systemic administration is 8 hours in ruminants. It varies depending on the route of administration; it is prolonged in animals with renal insufficiency.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Sodium laurilsulfate
Sodium starch glycolate type A
Microcrystalline cellulose
Silica colloidal anhydrous

Magnesium stearate

6.2 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

Keep the blisters in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Blister consisting of PVC/PE/PVDC top foil and aluminium bottom foil:

Carton with 1 blister of 5 intrauterine tablets
Carton with 2 blisters of 5 intrauterine tablets each (10 tablets)
Carton with 4 blisters of 5 intrauterine tablets each (20 tablets)
Carton with 10 blisters of 5 intrauterine tablets each (50 tablets)
Carton with 20 blisters of 5 intrauterine tablets each (100 tablets)
Carton with 40 blisters of 5 intrauterine tablets each (200 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

Eurovet Animal Health BV
Handelsweg 25
NL-5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 16849/4021

9. DATE OF FIRST AUTHORISATION

30 June 2011

10. DATE OF REVISION OF THE TEXT

May 2016

17 May 2016