<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovocycline Pessary 2000 mg intrauterine tablet for cattle
Tetracycline hydrochloride

2. STATEMENT OF ACTIVE AND OTHER 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

5 intrauterine tablets
10 intrauterine tablets
20 intrauterine tablets
50 intrauterine tablets
100 intrauterine tablets
200 intrauterine tablets

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:

Meat and offal 10 days
milk 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Eurovet Animal Health BV
Handelsweg 25
NL-5531 AE BLADEL
The Netherlands
Tel. ++31-497544300
Fax ++31-497544302

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTERS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovocycline Pessary 2000 mg intrauterine tablet for cattle
Tetracycline hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

Bovocycline Pessary 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 and manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

Long-term therapy requires careful monitoring to avoid super-infections (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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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10. WITHDRAWAL PERIOD

Withdrawal period:

Cattle:

Meat and offal 10 days
milk 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the blisters in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Use during pregnancy, lactation or lay

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

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.

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
Please refer to the section “adverse reactions”.

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

Any unused product or waste materials should be disposed of in accordance with national requirements. Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon 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

Package sizes:
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.


17 May 2016