SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OXTRA VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pessary contains:

Active substance:
oxytetracycline.....1 g
equivalent to oxytetracycline hydrochloride.....1.08 g

For a complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent intrauterine pessaries.

4. CLINICAL PARTICULARS

4.1. Target species

Cows.

4.2. Indications for use, specifying the target species

Cattle - therapy and prevention of bacterial infections of the genital tract caused by microorganisms sensitive to oxytetracyline, in particular in retained placenta and endometritis.

4.3. Contraindications

The product is contraindicated in subjects which have shown hypersensitivity to the tetracyclines in general or to any one of the excipients.

4.4. Special warnings for each target species

Repeated or prolonged use should be avoided, improve management procedures including cleanliness and disinfection.

4.5. Special precautions for use

Special precautions for use in animals

Use of the product should be based on sensitivity testing against bacteria isolated from the animals to be treated. If this should not be possible, therapy should be based on local (regional or from breeding establishments) epidemiological information regarding the susceptibility of the target bacteria.
Use of the product in a way not complying with the instructions supplied may increase the prevalence of bacteria resistant to the tetracyclines and may decrease the efficacy of treatment with other antibiotics of the same class or different classes, owing to potential cross-resistance.

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

Persons with known hypersensitivity to oxytetracycline, to other tetracyclines or to any of the excipients must avoid contact with the veterinary medicinal product. Wear gloves during administration of the product and have regard for the usual hygiene procedures.
Do not swallow. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the doctor.

4.6. Adverse reactions (frequency and seriousness)

Not known.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.7. Use during pregnancy or lactation

To be used in the period of the puerperium.
Use of Oxtra effervescent pessaries is not contraindicated in lactation.

4.8. Interaction with other medicinal products and other forms of interaction

None known.

4.9. Amounts to be administered and administration route

Administer by the intrauterine route.
Cows: 2-4 pessaries/day in a single administration (equivalent to 2-4 g of oxytetracycline).
Repeat, if necessary, after 24 hours.

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

No cases of symptoms due to overdosage have been reported.

4.11. Withdrawal periods

Meats and offal: 10 days
Milk: 84 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: anti-infective agents and antiseptics for intrauterine use. Antibiotics
ATCVet Code: QG51AA01

5.1. Pharmacodynamic properties

Oxytetracycline is a broad spectrum antibiotic active against most Gram-positive and Gram-negative bacteria, Chlamydiae, Rickettsiae, Mycoplasmas, Actinomycetes and some protozoa. Among the pathogens responsible for infections to the system genital in the cow, oxytetracycline is particularly efficacious against *Arcanobacterium pyogenes*, *Bacteroides*

spp., *Clostridium* spp., *E. coli*, *Fusobacterium necrophorum*, *Haemophilus* spp., *Klebsiella* spp., *Pasteurella* spp., *Proteus* spp., *Pseudomonas* spp., *Staphylococcus* spp., *Streptococcus* spp.
The pharmacological and pharmacokinetics properties and the low toxicity of OXTRA VETERINARY effervescent pessaries make the preparation particularly suitable for therapy and prevention of uterine infections.

5.2. Pharmacokinetic particulars

At the recommended doses for OXTRA VETERINARY effervescent pessaries, oxytetracycline rapidly reaches therapeutically efficacious levels against intrauterine pathogenic bacteria; these levels persist for up to 24-36 hours after administration. The limited capacity for absorption of oxytetracycline by the uterine wall ensures a localised antibiotic action in the lumen of the organ and the endometrium, the site of the required therapeutic effect.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Anhydrous lactose
Povidone
Microcrystalline cellulose
Citric acid, anhydrous
Sodium hydrogen carbonate
Sodium starch glycolate
Colloidal anhydrous silica
Magnesium stearate

6.2. Incompatibilities

Not applicable.

6.3. Shelf-life

The expiry date of the product is indicated on the packaging materials.

6.4. Special precautions for storage

Store below 25^0 C, in a dry place~~,~~ protected from light and sources of heat.

6.5. Nature and composition of immediate packaging

Blister formed by welded PVC/PVDC/PE/aluminium layers.

Box containing blisters with 36 intrauterine pessaries
Box containing blisters with 120 intrauterine pessaries

Not all packs 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 products should be disposed of in accordance with local requirements.

7. MANUFACTURER

FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia (Bologna), Italy.

8. REGISTRATION HOLDER

ROMAT Ltd. – HA'MAAPILIM 39/104 , HERZLIYA 46543

9. REGISTRATION NUMBER

083-17-92350

Approved on March 2020