Consumer leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. **NAME, FORM AND STRENGTH OF THE VETERINARY MEDICINE**

   OXTRA VETERINARY, effervescent pessaries for intrauterine use

2. **ACTIVE INGREDIENT** and its quantity in a dose unit

   Each pessary contains:

   Oxytetracycline HCl, equivalent to 1 g Oxytetracycline

   For inactive excipients – see section 13 ("Additional information")

3. **WHAT IS THE MEDICINE INTENDED FOR**

   In cows: therapy and prevention of bacterial infections of the genital tract caused by microorganisms sensitive to oxytetracycline, particularly retained placenta and endometritis.

   Therapeutic group: Broad-spectrum antibiotics.

4. **CONTRAINDICATIONS**

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

5. **SIDE EFFECTS**

   No side effects were reported for the product.

   Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link: https://sideeffects.health.gov.il

6. **TARGET SPECIES**

   Cows.

7. **DOSAGE AND ADMINISTRATION**

   Administer by the intrauterine route.

   Cows: 2-4 pessaries/day in a single administration. Repeat, if necessary, after 24 hours.

8. **HOW TO USE THE PRODUCT**

Wear gloves during administration of the product and have regard for the usual hygiene procedures.

9. **WITHDRAWAL PERIOD**

Before slaughter: 10 days.

Milk: 84 hours.

10. **WARNINGS**

- Special warnings for the use of the medicinal product in the target species

  Repeated or prolonged use should be avoided; improve the management of the cows regarding cleanliness and disinfection.

- Special warnings for safe use in animals

  Use of the product should be based on sensitivity testing against bacteria isolated from the animals to be treated. If this is not possible, therapy should be based on local epidemiological information (regional or from relevant establishments) regarding the susceptibility of the targeted 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 warnings to be taken by the person administering the veterinary medicinal product

  Persons with known hypersensitivity to oxytetracycline, to other tetracyclines or to any of the excipients, must avoid contact with the veterinary medicinal product. Do not swallow. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the doctor.

- Use during pregnancy or lactation of the treated animal

  To be used in the period after calving.

  Use of Oxtra veterinary is not contraindicated in lactation.

- Interaction with other medicinal products and other forms of interaction

  Not known.

- Overdose

No data is available. No cases of symptoms due to overdosage have been reported. Do not exceed the recommended dose.

- Incompatibilities

  Not applicable.

11. **STORAGE INSTRUCTIONS**

- Avoid poisoning! Keep this medicine and any other drug in a closed place out of reach and sight of children and/or infants to avoid poisoning.
- Do not use this medicine after the expiry date shown on the package. The expiry date refers to the last day of the month indicated.
- Storage conditions: To be stored at temperature not above 25ºC, in a dry place, protected from light and sources of heat.

12. **INSTRUCTIONS FOR DISPOSING OF THE PRODUCT / REMAINING PRODUCT AT THE END OF ITS USE**

Any unused veterinary medicinal product or waste materials derived from such medicinal products should be disposed of as toxic waste; Do not throw into the sewage system.

13. **ADDITIONAL INFORMATION**

- In addition to the active ingredient, the medicine also contains: Anhydrous lactose, Microcrystalline cellulose, Sodium hydrogen carbonate, Anhydrous citric acid, Povidone, Sodium starch glycolate, Magnesium stearate, Colloidal anhydrous silica
- What does the medicine look like and what is the content of the package – effervescent pessaries in a blister.
- Package sizes: Box containing 36 effervescent pessaries in blisters.
  Box containing 120 effervescent pessaries in blisters.

  Not all package sizes may be marketed.

Registration holder: Romat Ltd., 39/104 Hamaapilim St., Herzliya 46543

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Registration number of this medicine in the Ministry of Health State Medicine Registry: 083-17-92350