

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROXIMIN INTRAUTERINE PESSARIES VETERINARY

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pessary contains:

**Active substance:**

rifaximin.....300 mg

**Excipients** q.s. ....4 g

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Effervescent pessaries.

Orange oblong intrauterine tablets with clear, continuous rounded ends and split-point in the centre.

### 4. CLINICAL PARTICULARS

#### 4.1. Target species

Large ruminants and mares, sows and small ruminants.

#### 4.2. Indications for use, specifying the target species

For the therapy and prevention of infections of the female genital tract and more specifically: metritis, endometritis, cervicitis, vulvovaginitis, septic infections following delivery, placental retention, prophylaxis following manual or instrumental obstetric manoeuvres (dystocic deliveries).

#### 4.3. Contraindications

Do not administer to animals with known hypersensitivity to rifaximin (the active substance), or to any of the excipients listed in section 6.1.

#### 4.4. Special warnings for each target species

NA.

#### 4.5. Special precautions for use

##### Special precautions for use in animals

None.

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

None.

#### **4.6. Adverse reactions (frequency and seriousness)**

None.

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization 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, lactation or lay**

To be used in the puerperium.

The use of FATROXIMIN INTRAUTERINE PESSARIES VETERINARY during lactation is not contra-indicated.

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

None.

#### **4.9. Amounts to be administered and administration route**

Administer FATROXIMIN INTRAUTERINE PESSARIES VETERINARY by the vaginal-uterine route.

#### **Large ruminants and mares:**

- metritis, endometritis, cervicitis: 4 pessaries in one single administration or 2+2 pessaries at a 24-hour interval;
- vulvovaginitis: 1+1 pessary at a 24-hour interval;
- placental retention: 4 pessaries in one single administration.
- manual or instrumental obstetric manoeuvres (dystocic deliveries): 2 pessaries in one single administration.

#### **Sows and small ruminants:**

- metritis, endometritis, cervicitis, vulvovaginitis: 2 pessaries in one single administration or 1+1 pessaries at a 24-hour interval;
- placental retention: 2 pessaries in one single administration.
- manual or instrumental obstetric manoeuvres (dystocic deliveries): 1 pessary in a single administration.

In cases of placental retention, if the placenta was not detached within 12-24 hours following the treatment, 2 additional pessaries should be administered intrauterinely.

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

No effects due to overdose have been reported.

#### **4.11. Withdrawal periods**

No waiting time is required for milk or meat.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antibacterials for intrauterine use

ATCvet code: QG51AA06

### **5.1. Pharmacodynamic properties**

FATROXIMIN INTRAUTERINE PESSARIES VETERINARY is a preparation based on rifaximin, a synthetic antibiotic belonging to the ansamycin group.

The mechanism of action of rifaximin consists in the interaction with DNA-dependent RNA polymerase resulting in blocking of protein synthesis.

The spectrum of action of rifaximin principally comprises Gram-positive microorganisms, including anaerobes (streptococci, staphylococci, actinomycetes, clostridia, bacteroides and fusobacteria) and some Gram-negative microorganisms.

### **5.2. Pharmacokinetic particulars**

Pharmacokinetic studies reveal virtually zero passage through the uterine wall thus allowing excellent availability of rifaximin in the uterus and absence of residues in milk and meat.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Anhydrous Lactose

Microcrystalline cellulose

Sodium hydrogen carbonate

Anhydrous citric acid

Magnesium stearate

Silica, colloidal anhydrous

### **6.2. Incompatibilities**

None known.

### **6.3. Shelf life**

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

### **6.4. Special precautions for storage**

Do not store above 25<sup>0</sup>C, Keep in a dry place, away from light and heat sources.

### **6.5. Nature and composition of immediate packaging**

#### Immediate container

PVC/PVDC/PE blister closed by heat-sealing to aluminium foil.

#### Outer container

Box containing 12 pessaries in blister strips

Box containing 36 pessaries in blister strips

Not all pack sizes may be marketed.

### **6.6. Special precautions for the disposal of unused veterinary medicinal products 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. Manufacturer:**

FATRO S.p.A. - Via Emilia, 285 – 40064, Ozzano Emilia (Bologna), Italy.

**8. Registration Holder:**

Romat LTD., Ha'maapilim 39/104, Herzliya 4654327

**9. Registration Number:**

081-41-92212

**Revised in July 2021 according to MoH guidelines.**

