SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROXIMIN Dry Cow intramammary ointment veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml intramammary syringe contains:
Active substance:
rifaximin.....100 mg

Excipients: q.s. to.....5 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary ointment. Homogeneous orange-red ointment

4. CLINICAL PARTICULARS

4.1. Target species

Cows, buffalo.

4.2. Indications for use, specifying the target species

Fatromixine is indicated at the beginning of the dry period of the cow, buffalo and other large ruminants: to treat exisiting subclinical infections to prevent possible infections during drying off to prevent acute mastitis that can arise on delivery at beginning of milk production.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings for each target species

Do not use the udders of treated animals for food purposes.
The treatment must be performed not beyond 7 weeks prior to the presumed date of calving.

4.5. Special precautions for use

Special precautions for use in animals

If possible, the veterinary medicinal product should be used on the basis of antibiogram results. Improper use of the product may lead to an increase in the incidence of bacteria resistant to rifaximin.
Special attention must be given to improving rearing practices to avoid all possible stressing conditions.
Repeated or prolonged use of the product should be avoided, improving management and

disinfection procedures.

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

People with known sensitivity to rifaximin or other ansamycins must avoid contact with the product.
In case of accidental contact, wash the hands and the other skin areas involved carefully.
In case of accidental contact with the eyes and mucosae, rinse immediately with plenty of water.

4.6. Adverse reactions (frequency and seriousness)

Not reported.

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

The product should be used during pregnancy, at the time of drying off.

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

None known.

4.9. Amounts to be administered and administration route

One intramammary syringe for each teat after the last milking at the beginning of the dry period.
Each teat must be milked and full dryness must be secured. Clean and disinfect each teat; afterwards inert the Fatroximin syringe; remove the protective cover, introduce the hub into the teat canal and inject the whole contents.
Remove the hub and hold the tip of the teat in one hand while the second hand massages the teat in upward direction. Thereafter massage every quarter of the udder with both hands in long movements in upward direction to ensure even distribution of the ointment in each quarter of the udder.

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

There are no reported overdose symptoms related to the use of the medicinal product.

4.11. Withdrawal periods

For meat: No waiting time is required.
For milk: If the dry period lasts more than 42 days, the waiting period is nil. If the dry period is shorter than 42 days, the milk obtained from the first 15 milkings must not be used.
A milk sample from the treated cow should be sent to test for permitted materials prior to

including the milk in the pooled production of the herd.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for intramammary use
ATC Vet Code: QJ51XX01

5.1. Pharmacodynamic properties

FATROX1MIN Dry Cow intramammary ointment is a preparation based on rifaximin, a synthetic antibiotic belonging to the ansamycin family.
The mechanism of action of rifaximin involves interaction with DNA-dependent RNA polymerase, with consequent block of protein synthesis.
The spectrum of action of rifaximin includes the principal bacteria responsible for bovine mastitis: *Staphylococcus aureus* (including penicillin-resistant strains), *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Actinomyces pyogenes*.

5.2. Pharmacokinetic particulars

The pharmacokinetic studies performed demonstrate virtually zero passage through the intramammary epithelium, thus permitting excellent availability of rifaximin in the treated quarter.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glycerol monostearate 40-55
Macrogol cetostearyl ether
Liquid paraffin, light

6.2. Incompatibilities

Not known

6.3. Shelf-life

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

6.4. Special precautions for storage

To be stored at temperature not above 25°C. Protect from light.

6.5. Nature and composition of the immediate packaging

5 ml intramammary syringes in polyethylene.

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. 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:
081-42-92213

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