Consumer Leaflet for a Veterinary Product

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

For veterinary use only

1. Name of the veterinary medicine, form and strength

Fatroximin Dry Cow Intramammary Ointment Veterinary

2. Active ingredient and its quantity in a single dose:

Each 5 ml syringe contains:

Rifaximin 100 mg

For a full list of excipients, see section 13.

3. What is the medicine intended for

For use at the beginning of the dry period to treat subclinical udder infections, to prevent possible infections during drying off and to prevent acute mastitis that can arise on delivery and/or at the beginning of milk production.

Therapeutic group:

antibacterials for intramammary use.

4. Contra-indications

Do not use in animals with hypersensitivity to the active ingredient or to any one of the excipients.

5. Side effects

Side effects were not reported.

Reporting of suspected adverse reactions

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 animals

Cows and buffalos.

7. Dosage and administration

One intramammary syringe per udder quarter after the final milking at the beginning of the dry period. Each mammary quarter must be milked and full dryness must be secured. Clean and disinfect the teats, then insert the Fatroximin syringe. Remove the protection cover, introduce the hub into the teat canal and inject the entire content of the syringe. 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.

8. How to use the product

See drawings at the end of the leaflet.

9. Withdrawal period

Meat: no withdrawal is required.

Milk: If the dry period is longer than 42 days, the withdrawal period is zero.
If the dry period is shorter than 42 days**,** do not use the milk of the first 15 milkings. Send a sample of the milk of the treated cow to be tested for allowed substances before the milk will be entered to the milk reservoir of the herd.

10. Warnings

- **Special warnings for use of the medicine in target animals**
  - 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.

- **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, while improving management and disinfection procedures.

- **Special precautions concerning the safety of the person administering the medicinal product**
  - 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.

- **Pregnancy and lactation in target animals**
  The product should be used during pregnancy, at the time of drying off.

- **Interaction with other medicinal products and other forms of interaction**
  None known.

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

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after its expiration date (exp. date) as it appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions: Do not store above 25^0C and protect from light.

12. Instructions for disposing of the product / remaining product at the end of its use

Any unused veterinary medical product or any waste remaining after using the veterinary medical product must be disposed of as toxic waste; do not throw into the sewage system.

13. Additional information

- **in addition to the active ingredient, this medicine also contains:**
  Glycerol monostearate 40-55, Macrogol cetostearyl ether, Light liquid paraffin

- **How does the medicine look like and what is the content of the package:**

5 ml of homogeneous orange-red ointment for intramammary use.

Packages of 4 or 12 syringes.

Not all pack sizes may be marketed.

- **Registration holder:**
  ROMAT LTD., HA'MAAPILIM 39/104 , HERZLIYA 4654327

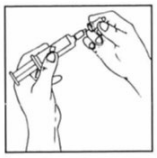
- **Manufacturer**:
  FATRO S.P.A.
  VIA EMILIA 285 - 40064 ,OZZANO EMILIA, BOLOGNA, ITALY

- **Registration number of this medicine in the Ministry of Health State Medicine Registry:**
  081-42-92213

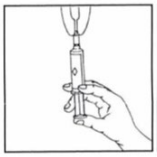
- **Revised in July 2021 according to MoH guidelines.**

Using the intramammary syringe:

Partial-insertion:

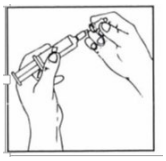


1. Remove the protection cover

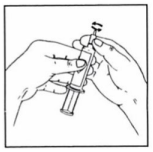


2. Insert the medicine.

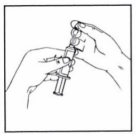
Full insertion:



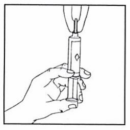
1. Remove the protection cover



2. disconnect the "partial-insertion" device by twisting



3. remove the "partial-insertion" device



4. Insert the medicine.