Vivonex DC

(Rifaximin) Intramammary Suspension

Dry Cow

ویوونیکس ۔ڈی سی آئی ایم ایم سسپنشن

۵ ملی لیٹر x ۱۲ انجیکٹر

5ml x 12 Injector

1. COMPOSITION QUALITATIVE ET QUANTITATIVE:
Each 5ml Injector Contains:
Active ingredient(s):
Rifaximin.100 mg

2. PHARMACEUTICAL FORM:
Intramammary ointment

3. CLINICAL INFORMATION:

3.1 Target species:
Cattle (cows to dry off)

3.2 Indications for use specifying target species:
Prevention of bacterial infections of the udder during drying off, caused by organisms sensitive to rifaximin.

3.3 Contraindications:
Do not administer during the lactation period.

3.4 Special warnings for each target species:
None

3.5 Special precautions for use:
i) Special precautions for use in animals In the Presence of clinical mastitis, another treatment must be considered.
ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals Due to the coloring of
iii) the product, handle the injectors with gloves.

3.6 ADVERSE REACTIONS (FREQUENCY AND SEVERITY):
None known

3.7 Use in case of gravidity, lactation or laying:
The intramammary tube is intended for dry cows and therefore, in most cases, for pregnant cows.

3.8 DRUG INTERACTIONS AND OTHER FORMS OF INTERACTIONS:
None known

3.9 Dosage and method of administration:
Before instilling the injector, the udder must be completely milked.

Care must be taken to avoid contamination of the injector tip.

100 mg of rifaximin per quarter, i.e. 1 injector per quarter, administered intramammary after the last milking and after disinfection of the end of the teat. After administration, dip the teats in a disinfectant solution.

3.10 OVERDOSE (SYMPTOMS, EMERGENCY RESPONSE, ANTIDOTES), IF NECESSARY:
Not known

3.11 Withdrawal period:
Milk: More than 4 weeks after drying off: 0 h - less than 4 weeks after drying off: 11 days (22 milkings)
Meat & Offal: 0 h

4. PHARMACOLOGICAL PROPERTIES:
Pharmacotherapeutic group: ansamycins

4.1 Pharmacodynamics properties:
Rifaximin is an antibiotic belonging to the ansamycin family. It presents the mechanism of action of rifamycins acting directly at the level of transcription by interaction with RNA-polymerase, DNA dependent. It thus prevents the synthesis of messenger RNA and proteins.

The spectrum of action of rifaximin encompasses, in particular, the main germs responsible for mammals: Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae et Streptococcus uberis, Actynomyces pyogenes.

It is estimated that the germs are sensitive when the MIC is 1 µg/ml, of intermediate sensitivity when the MIC is 2 µg/ml and resistant for MICs of 4 µg/ml.
The sensitivities of the major pathogenic germs isolated to drying off in cattle are as follows:

Microorganisms	CMI 50% (µg/ml) Drying up
Staphylococcus aureus	0,09
Streptococcus uberis	0,143
Streptococcus agalactiae, dysgalactiae	0,246
Actynomyces pyogenes	< 0,008

4.2 Pharmacokinetic characteristics
Pharmacokinetic studies indicate that intramammary application of rifaximin leads to negligible systemic absorption of the active ingredient.

5. PHARMACEUTICAL INFORMATION

5.1 Incompatibilities
None known

5.2 Shelf life
- 2 years when stored under recommended conditions.
- Use immediately after opening the syringe.

5.3 Special storage precautions
Store at room temperature (15 - 25°C)

5.4 Nature and composition of primary packaging
Box of 12 x 5ml Plastic syringes.

5.5 Special precautions to take when disposing of medicines
Unused veterinary medicines or waste derived from the use of these medicines

Any unused veterinary medicinal products or waste derived from these medicinal products should be disposed of in accordance with local requirements.

MANUFACTURED BY:
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