ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fatroximin spray solution for topical use for cattle, sheep, goats, swine, horses, rabbits, dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 200 ml gas cylinder contains:

Active substance:

rifaximin……..……..0.5 g

Excipients:

Patent blue V (E131)…… 0.2g

Propyl gallate (E310)……...0.1 g

Other excipients and propellant q.s. to……..…142 g

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spray solution for topical use.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle, sheep, goats, swine, horses, rabbits, dogs and cats.

4.2. Indications for use, specifying the target species

Prevention and therapy of infections to the integumentary system and adnexa, due to pathogens sensitive to rifaximin, principally Gram-positive bacteria, including anaerobes (streptococci, staphylococci, actinomycetes, clostridia, bacteroides, fusobacteria) and certain Gram-negative bacteria.

More specifically: foot rot, interdigital dermatitis, foot lesions in general, pyodermatitis, abrasions, sores, ulcers, rhagades, postsurgical and traumatic wounds.

4.3. Contraindications

Do not use in animals with known hypersensitivity to rifaximin or to any of the excipients.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for use in animals

Do not spray in the eyes or in adjacent areas.

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

Do not inhale and avoid any contact with the eyes and the other mucosae.

In case of accidental contact, wash the hands and other contaminated skin areas carefully.
In case of accidental contact of the eyes and mucosae, immediately rinse very well with water.
Keep away from ignition sources.
Do not spray onto flames or onto any incandescent material.
People with known sensitivity to rifaximin or to other ansamycins must avoid contact with the product.

4.6. Adverse reactions (frequency and severity)
None known.

4.7. Use during pregnancy, lactation or lay
Use of Fatroximin spray for topical use is indicated during pregnancy and lactation.

4.8. Interaction with other medicinal products and other forms of interaction
Not known.

4.9. Amounts to be administered and administration route

Shake carefully prior to use.
Administer by the topical route.
Cleanse the part involved and spray for 1-3 seconds, equivalent to approximately 2-9 mg of rifaximin per application.
The treatment may be repeated once or twice a day until cure, on average for 3-5 days.

In case of foot rot and other foot lesions, clean and carefully pare the corneal tissue so as to completely expose the infected part and administer Fatroximin spray for topical use, being careful to apply the product over the entire site of infection.
In mild infections and in zones not particularly subject to abrasion, recovery may be obtained with just a single administration.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary
Symptoms of overdose related to use of the medicinal product are not reported.

4.11. Withdrawal periods
Meat and offal:0 days.
Milk: 0 hours.

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: antibiotics for topical use
ATCvet Code: QD06AX11

5.1. Pharmacodynamic properties

Fatroximin spray for topical use 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 principally includes the Gram-positive bacteria, including anaerobes (streptococci, staphylococci, actinomycetes, clostridia, bacteroides, fusobacteria) and certain Gram-negative bacteria.

5.2. Pharmacokinetic particulars

Rifaximin is poorly absorbed systemically, whatever the administration route.
Pharmacokinetic studies for repeated cutaneous administration performed with Fatroximin spray for topical use highlight the absence of rifaximin in the plasma, in muscle and in the fat below the cutaneous application site, in addition to not being present in the milk of the treated animals.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Patent blue V (E131)
Propyl gallate (E310)
Propylene glycol
Ethanol anhydrous
Butane/Propane (75:25), as propellent

6.2. Incompatibilities

Not known.

6.3. Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4. Special precautions for storage

Inflammable product.
Container under pressure: protect from light and from high temperatures.
Do not pierce or burn even after use.
Does not contain propellent gases considered damaging for the ozone.

6.5. Nature and composition of immediate packaging

200 ml, equivalent to 142 g, aluminium gas cylinder, internally coated with a protective epoxy- amino-phenolic resin.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

CY00075V

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/4/2004, 14/4/2014

10. DATE OF REVISION OF THE TEXT

22/09/2014

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.