S4

Evanix 100 mg / mℓ Injection

VETERINARY MEDICINE. FOR ANIMAL USE ONLY.

SCHEDULING STATUS
S4

PROPRIETARY NAME AND DOSAGE FORM
EVANIX 100 mg / mℓ (injection)

COMPOSITION
Each 1,0 mℓ solution contains:
Enrofloxacin 100 mg
Preservatives:
Benzyl alcohol 2 % *m/v*
n-Butyl alcohol 3 % *m/v*

PHARMACOLOGICAL CLASSIFICATION
C 17.1.6 : Antibacterials – Quinolones

PHARMACOLOGICAL ACTION
Enrofloxacin inhibits the bacterial enzyme DNA-gyrase, which is essential for bacterial replication, transcription and recombination. *In-vitro* sensitivity does not necessarily imply *in-vivo* efficacy.

INDICATIONS
EVANIX is indicated for the treatment of respiratory disease associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma* spp. in cattle.

CONTRA-INDICATIONS
No contra-indications are known.

WARNINGS
Withdrawal period:
Edible tissues: 14 days
Milk: 3 days
Safety of **EVANIX** in pre-weaning calves has not been established.

DOSAGE AND DIRECTIONS FOR USE
A single dose of 7,5 mg / kg should be administered.
The volume should not exceed more than 15 mℓ per injection site.
EVANIX should be administered by subcutaneous injection only.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS
Cartilage lesions may occur in calves.
Normal sterile precautions should be taken.
Special precautions should be taken by the person administering the product to animals. **EVANIX** is an alkaline solution. Wash any splashes from skin or eyes immediately with water.
Do not eat, drink or smoke while using the product.

Special precautions for the disposal of unused product or waste materials:
Empty containers and packaging should be disposed of carefully with other waste.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Lethargy, muscle tremors, slow gait, mild diarrhoea and elevated CPK and AST activities are observed at higher doses administered repetitively.
Treatment is symptomatic and supportive.

IDENTIFICATION
A clear yellow aqueous solution filled in a glass vial. When examined under suitable conditions of visibility it is practically free from foreign particles.

PRESENTATION
100 mℓ Amber glass vial with rubber stopper and scarlet-red flip-off aluminium overcap.

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Protect from light.
Store in unit carton until required for use.
Keep out of reach of children and uninformed persons.
The solution should be used or discarded within 28 days of opening.

REGISTRATION NUMBER
10/17.1.6/15

REGISTRATION HOLDER
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