

FOR VETERINARY USE ONLY (cattle and swine)

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

DANOVET 2,5 % (Solution for injection)

COMPOSITION

Each 1,0 ml solution contains:

Danofloxacin mesylate equivalent to 25,0 mg danofloxacin

Preservatives:

Phenol 0,25 % m/v

PHARMACOLOGICAL CLASSIFICATION

C.21.9 Antimicrobial agents (Others).

PHARMACOLOGICAL ACTION

Following subcutaneous or intramuscular administration to cattle and after intramuscular administration to swine, **DANOVET 2,5 %** is rapidly absorbed and has a marked affinity for lung tissue. Within one-hour, levels in the lung are approximately four-fold those found in plasma.

DANOVET 2,5 % exerts its activity by inhibition of the bacterial DNA gyrase, the enzyme is involved in DNA replication. The inhibition of DNA gyrase is lethal to bacteria and **DANOVET 2,5 %** has been shown to be rapidly bactericidal.

DANOVET 2,5 % shows a high level of *in vitro* activity against the following pathogens:

Gram-negative:

Escherichia coli, *Bordetella bronchiseptica*, *Haemophilus somnus* (*Histophilus somni*), *Mannheimia* (*Pasteurella*) *haemolytica*, *Pasteurella multocida*, (including atrophic rhinitis strains), *Salmonella dublin*, *Salmonella enteritidis*, *Salmonella typhimurium*, *Salmonella* spp, *Actinobacillus* (*Haemophilus*) *pleuropneumoniae*.

Gram-positive:

Corynebacterium pyogenes (*Trueperella pyogenes*), *Staphylococcus aureus*, *Streptococcus* spp, *Streptococcus suis*.

Mycoplasmas:

Mycoplasma bovis, *Mycoplasma bovis genitalium*, *Mycoplasma* (*dispar*), *Mycoplasma hyopneumoniae*, *Mycoplasma hyosynoviae*.

In vitro sensitivity does not necessarily imply *in vivo* efficacy.

INDICATION

Cattle (*Dairy cattle, beef cattle and calves*):

DANOVET 2,5 % is indicated for the treatment of bovine respiratory disease (shipping fever, pneumonia) in beef cattle, dairy cattle and calves caused by *Mannheimia* (*Pasteurella*) *haemolytica* and *Pasteurella multocida*, and enteric infections in calves caused by *Salmonella* spp and *Escherichia coli*.

Swine:

DANOVET 2,5 % is indicated for the treatment of respiratory disease caused by *Actinobacillus* (*Haemophilus*) *pleuropneumonia* and *Pasteurella multocida*.

CONTRA-INDICATIONS

DANOVET 2,5 % should not be used in animals with renal function impairment.

WARNINGS

Cattle:

- Milk from treated cows must not be used for human consumption during treatment or for 24 hours (2 milkings) after the last treatment.
- Do not administer within five days of slaughter.

Swine:

- Do not administer within 21 days of slaughter.

DOSAGE AND DIRECTIONS FOR USE

Cattle:

DANOVET 2,5 % can be administered by either intramuscular or subcutaneous routes at a dose rate of 1 ml / 20 kg body mass (1,25 mg danofloxacin / kg body mass). Do not inject more than 20 ml per injection site.

Treatment should be administered once daily and repeated at 24-hour intervals for a total of three to five treatments.

Swine:

DANOVET 2,5 % can be administered by the intramuscular route at a dose rate of 1 ml / 20 kg body mass (1,25 mg danofloxacin / kg body mass).

Treatment should be administered once daily and repeated at 24-hour intervals for a total of three treatments.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

None.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Gross overdosage can result in reluctance to move and stiffness. Gross overdosage can result in intra-renal crystallization. Treatment is symptomatic and supportive.

IDENTIFICATION

A pale-yellow clear solution free of particulate matter.

PRESENTATION

DANOVET 2,5 % is packed in 50 ml or 100 ml amber glass vial with a dark grey bromobutyl rubber stopper and an aluminum center tear-off seal.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect against sunlight. Do not refrigerate. After withdrawal of the first dose, the broached vial may be stored at or below 25 °C for 28 days.

Keep out of reach of children and uninformed persons.

REGISTRATION NUMBER

07/21.9/02

EXPORT COUNTRIES

Namibia: V13/17.1.6/1195 NS2

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DATE OF PUBLICATION OF THIS PACKAGE INSERT

03 March 2012

