

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 bovigenitalium*, *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]

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

KYRON ANIMAL HEALTH (PTY) LTD

Reg. No. 2004/021847/07,

Unit 45A, 45 Parkview Street,

Highway Business Park,

Ext 31, Roohuiskraal,

Centurion,

South Africa.

Tel: 010 880 0778.

DATE OF PUBLICATION OF THIS PACKAGE INSERT

03 March 2012



SKEDULERING STATUS

S4

EIE NAAM EN DOSEERVORM

DANOVET 2,5% (Oplossing vir inspuiting)

SAMESTELLING

Elke 1,0 ml oplossing bevat:

Danofloksasien mesilaat gelykstaande aan 25,0 mg danofloksasien

Preserveermiddels:

Fenol 0,25 % m/v

FARMAKOLOGIESE KLASSIFIKASIE

C.21.9 Antimikrobiese middels (Ander).

FARMAKOLOGIESE AKSIE

Na onderhuidse of binnespierre toediening aan beeste en na binnespierre toediening aan varke, word **DANOVET 2,5 %** vinnig geabsorbeer en het 'n duidelike affiniteit vir longweefsel. Binne een uur is vlakke in die longe ongeveer viervoudig dié wat in plasma voorkom.

DANOVET 2,5 % oefen sy aktiwiteit uit deur inhibisie van die bakteriële ensiem DNA-gyrase, die ensiem is betrokke by DNA-replikasie. Die inhibisie van DNA-gyrase is dodelik vir bakterieë en daar is getoon dat **DANOVET 2,5 %** spoedig bakteriedodend is.

DANOVET 2,5 % toon 'n hoë vlak van in vitro-aktiwiteit teen die volgende patogene:

Gram-negatief:

Escherichia coli, *Bordetella bronchiseptica*, *Haemophilus somnus* (*Histophilus somni*), *Mannheimia* (*Pasteurella*) *haemolytica*, *Pasteurella multocida*, (insluitend atrofiese rinitisstamme), *Salmonella dublin*, *Salmonella enteritidis*, *Salmonella typhimurium*, *Salmonella* spp, *Actinobacillus* (*Haemophilus*) *pleuropneumoniae*.

Gram-positief:

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

Mikoplasmas:

Mycoplasma bovis, *Mycoplasma bovigenitalium*, *Mycoplasma dispar*, *Mycoplasma hyopneumoniae*, *Mycoplasma hyosynoviae*.

In vitro sensitiwiteit impliseer nie noodwendig *in vivo* doeltreffendheid nie.

AANDUIDING

Beeste (melkbeeste, vleisbeeste en kalwers):

DANOVET 2,5 % word aangedui vir die behandeling van beesrespiratoriese siekte (longontsteking) by vleisbeeste, melkbeeste en kalwers wat veroorsaak word deur *Mannheimia* (*Pasteurella*) *haemolytica* en *Pasteurella multocida*, en enteriese infeksies by kalwers wat veroorsaak word deur *Salmonella* spp en *Escherichia coli*.

Varke:

DANOVET 2,5 % word aangedui vir die behandeling van respiratoriese siektes wat veroorsaak word deur *Actinobacillus* (*Haemophilus*) *pleuropneumonie* en *Pasteurella multocida*.

KONTRA-INDIKASIES

DANOVET 2,5 % moet nie by diere met verswakte nierfunksie gebruik word nie.

WAARSKUWINGS

Beeste:

- Melk van behandelde koeie mag nie tydens behandeling, vir menslike gebruik, gebruik word nie of vir 24 uur (2 melkings) na die laaste behandeling.
- Moet nie binne vyf dae voor slagting toedien nie.

Varke:

- Moet nie binne 21 dae voor slagting toedien nie.

DOSIS EN GEBRUIKSAANWYSINGS

Beeste:

DANOVET 2,5 % kan deur óf binnespierre óf onderhuidse roetes toegedien word teen 'n dosis van 1 ml / 20 kg liggaamsmassa (1,25 mg danofloksasien / kg liggaamsmassa). Moenie meer as 20 ml per inspuitplek inspuit nie.

Behandeling moet een keer per dag toegedien word en met 24-uur-tussenposes herhaal word vir 'n totaal van drie tot vyf behandelings.

Varke:

DANOVET 2,5 % kan binnespiers toegedien word teen 'n dosis van 1 ml / 20 kg liggaamsmassa (1,25 mg danofloksasien / kg liggaamsmassa).

Behandeling moet een keer per dag toegedien word en met tussenposes van 24 uur herhaal word vir 'n totaal van drie behandelings.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS

Geen.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Oormatige oordosering kan tot onwilligheid om te beweeg en styfheid lei. Oordosering kan tot kristallasie in die niere lei. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

'n Liggeel helder oplossing vry van deeltjies.

AANBIEDING

DANOVET 2,5 % is verpak in 'n 50 ml of 100 ml amberkleurige glasflessie met 'n donkergrys broombutielrubberprop en 'n aluminium middelste afskeursel.

BERGING INSTRUKSIES

Stoor by of onder 25 °C. Beskerm teen sonlig. Moenie in die yskas sit nie. Na onttrekking van die eerste dosis, kan die flessie vir 28 dae by of onder 25 °C gestoor word.

Hou buite die bereik van kinders en oningeligte persone.

REGISTRASIENOMMER

07/21.9/02

UITVOER BESONDERHEDE:

Namibië: V13/17.1.6/1195 NS2

NAAM EN BESIGHEIDSDRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

KYRON DIEREGESONDHEID (EDMS) BPK

Reg. Nr. 2004/021847/07,

Eenheid 45A, Parkviewstraat 45,

Highway Business Park,

Uitbr. 31, Roohuiskraal,

Centurion

Suid-Afrika.

Tel: 010 880 0778.

DATUM VAN PUBLIKASIE VAN HIERDIE BYSLUITER

03 Maart 2012