QUINOFLOX 100 mg/ml

Solution for injection

Composition:
Enrofloxacin .....100 mg
Excipient ad. ..... 1 ml

Pharmacodynamic properties
Enrofloxacin is a bactericidal drug, active, even at low concentrations, against a wide range of Gram positive and Gram negative bacteria and mycoplasmas : *E. coli, Haemophilus spp., Pasteurella spp., Mycoplasma bovis, Klebsiella pneumoniae.*
Enrofloxacin inhibits primarily the bacterial DNA gyrase , an enzyme responsible for controlling the supercoiling of bacterial DNA during replication. Resealing of the double stranded helix is inhibited resulting in an irreversible degradation of the chromosomal DNA. Enrofloxacin also possesses activity against bacteria in the stationary phase by an alteration of the phospholipid cell wall permeability.

Pharmacokinetic data
The pharmacokinetics of enrofloxacin are such that oral and parenteral administration, either IM, SC or IV, lead to similar serum levels.
Enrofloxacin possesses a high distribution volume. In target species and laboratory animals, tissue levels were found to be 2-3 higher than serum levels.
Maximum concentrations are reached in 1 - 2 hours, maintaining bactericidal action in target tissues during 24 hours.
High concentrations can be expected in lungs, liver, kidneys, skin, bone and the lymphatic system. Enrofloxacin reaches also the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals.

Indications
Cattle
Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. *pasteurellosis, mycoplasmosis, coli-bacillosis, coli-septicaemia and salmonellosis).*
Secondary bacterial infections subsequent to viral infections (e.g. viral pneumonia) where clinical experience, supported when possible by antibiogram-sensitivity testing, indicates enrofloxacin as the drug of choice.

Pigs
Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. *pasteurellosis, mycoplasmosis, coli-bacillosis* and *coli-septicaemia)* and multifactorial diseases such as atrophic rhinitis and enzootic pneumonia where clinical experience, supported when possible by antibiogram-sensitivity testing, indicates enrofloxacin as the drug of choice.

Target species
Cattle and pigs

Dosage and administration
To ensure correct dosage, body weight should be determined as accurately as possible.

Cattle:
For respiratory and alimentary tract infections in cattle and secondary bacterial infections : Administer by **subcutaneous injection** 2.5 mg enrofloxacin per kg b.w.), daily during 3 days (Equivalent to 2.5 ml QUINOFLOX per 100 kg b.w.).
This dose may be doubled to 5 mg/kg b.w. (Equivalent to 5 ml QUINOFLOX per 100 kg b.w.) during 5 days for the treatment of salmonellosis and complicated respiratory disease.
Do not administer more than 10 ml at the same injection site.

Pigs:
For respiratory and alimentary tract infections in pigs and secondary bacterial infections : Administer by **intramuscular injection** 2.5 mg enrofloxacin per kg b.w. , daily during 3 days (Equivalent to 2.5 ml QUINOFLOX per 100 kg b.w.). This dose may be doubled to 5 mg/kg b.w. (Equivalent to 5 ml QUINOFLOX per 100 kg b.w.) during 5 days for treatment of salmonellosis and complicated respiratory disease.

Pigs : Do not administer more than 2,5 ml at the same injection site.
Sows : Do not administer more than 5 ml at the same injection site.

Withdrawal period
Cattle:
Following intravenous injection:
Meat and offal: 5 days.
Milk: 3 days.
Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.

Pigs:
Meat and offal: 13 days.

Adverse reactions
Local tissue reactions may occasionally occur at the injection site. Normal sterile precautions should be taken.

Use during pregnancy, lactation or lay
There is no restriction on the use of this product during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction
Do not administer with non-steroid anti-inflammatory agents.
Antagonist effects may appear with concomitant administration of macrolides or tetracyclines.

Pack Sizes :
100 and 250 ml vials.

MAH: Global Vet Health; Authorised Manufacturer: s.p.® veterinaria, s.a.

Ctra. Reus-Vinyols Km. 4,1 - P. O. Box. 60 - Phone +34 977 850 170* - Fax +34 977 850 405
43330 RIUDOMS (Tarragona) - SPAIN - **www.spveterinaria.com**

QUINOFLOX

Injectable
ENROFLOXACIN 10%

Don't let them hurt you !

s.p.® veterinaria

PROBLEMS WITH INJECTION ?

WE HAVE THE SOLUTION !

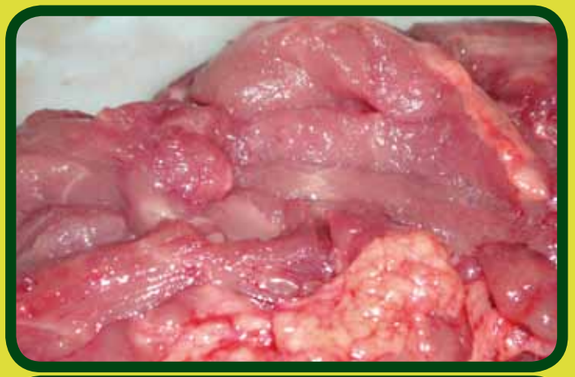
Comparative assay between QUINOFLOX injectable and Reference product with alkaline pH. Conducted with fattening pigs at PHATOPHY (National Veterinary School of Lyon, France)

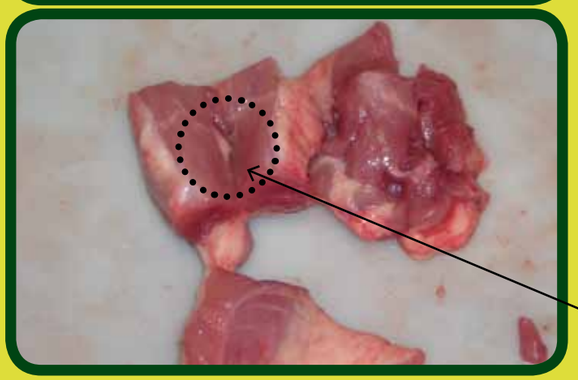
Intramuscular injection of enrofloxacin may cause important lesions at the inoculation site. Injection is more painful and the affected muscle parts are often cut out at slaughter, decreasing the carcass value.

Injuries observed: Muscle dissociation due to hemorrhagic infiltration and edema. Multifocal necrosis of muscle fibers with inflammatory infiltration of macrophages and polymorphonuclear cells.

Injectable preparation with high pH may cause such lesions. The pH found in enrofloxacin injection brands varies from 11,5 to 13

The OCDE qualifies injections with pH ≥ 11,5 into Category 1: causing possible destruction of tissues and visible necrosis production.

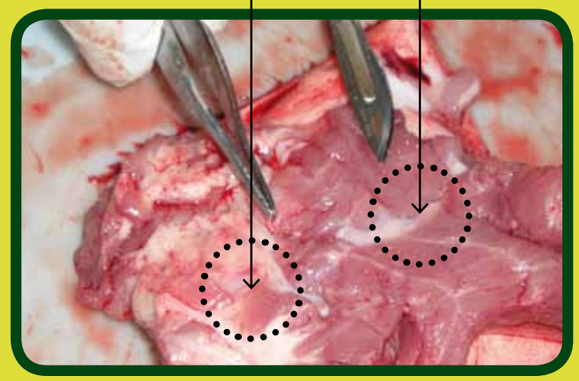




Field tests confirmed that 90 % of injected animals showed a significant reduction of inflammation at the injection site.

Injection point N°2.
No negative reaction

Injection point N°1.
No negative reaction



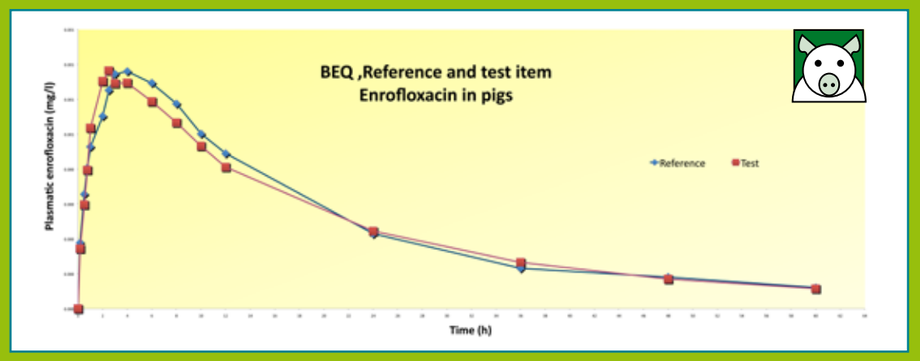
Injection point nº 3
No negative reaction

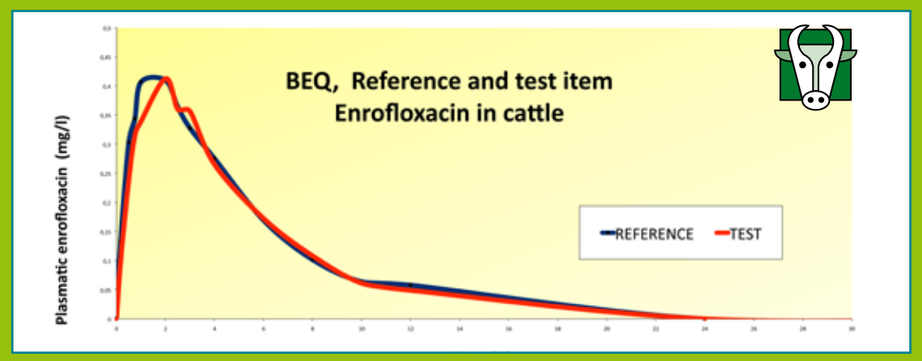
QUINOFLOX injectable is formulated as a weak acid solution, pH: 4,5

- **Less painful injection. INCREASE ANIMAL WELFARE at treatment.**
- **DECREASE of muscle lesions, necrotic and fibrinous tissues.**

SAME FIELD EFFICACY AND SAME STABILITY

Bioequivalence study of QUINOFLOX formulation compared to Reference Enrofloxacin injection Alkaline pH. SPCEN INVEST XXI





Dose: 2,5 mg/Kg b.w./day. Equivalent to 2,5 ml / 100 kg b.w.