VETOQUINOL	Nom du produit : FORCYL CATTLE SWINE MY	
Créé par : A.STIFANI	Référence article : 1118 F L	
le :	Dimensions : 160x120 mm	
Visa :	1 couleur	
	281U	

Use therefore according to the benefit/risk assessment carried out by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction: None known.

Overdose (symptoms, emergency procedures, antidotes): In cattle, lesions of the joint cartilage were observed in animals treated at 10 mg/kg or 30 mg/kg for three times the recommended treatment duration, but did not induce clinical signs. Moreover, no other signs of overdosage was observed throughout this study.

In pigs, lesions of the joint cartilage, potentially leading to difficulties in movement, were observed in some animals treated at three times the recommended dose and treatment duration.

Overdosage may cause signs such as acute neurological disorders which should be treated symptomatically.

Incompatibilities: In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

DOSAGE FORMS AND PACKAGING AVAILABLE

Amber type II glass vial closed with a Chlorobutyl rubber stopper and aluminium cap or flip cap

Pack sizes:

Cardboard box containing one 50 mL vial
Cardboard box containing one 100 mL vial
Cardboard box containing one 250 mL vial

Not all pack sizes may be marketed.

DATE OF REVISION OF PACKAGE INSERT: September 2019.

REGISTRATION NUMBER: MALXXXXXXXXXX

NAME AND ADDRESS OF MANUFACTURER
VETOQUINOL S.A
Magny-Vernois, 70200 Lure, France

NAME AND ADDRESS OF REGISTRATION HOLDER
GLADRON CHEMICALS SDN. BHD.
No.7, Jalan TP7,
UEP Industrial Park,
40400 Shah Alam,
Selangor Darul Ehsan, Malaysia

1118 F

vetoquinol

FORCYL®

160mg/mL, solution for injection for Swine and Cattle

FORMULATION

Each mL contains:
Marbofloxacin . . . . . 160 mg
Benzyl alcohol . . . . . 15 mg

PRODUCT DESCRIPTION

A yellow greenish/yellow brownish solution for injection in cattle and swine.

INDICATIONS

In fattening pigs: Treatment of respiratory tract infections caused by susceptible strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida.*

In weaned piglets: Treatment of intestinal infections caused by susceptible strains of *Escherichia coli*

In post-partum sows: Treatment of metritis mastitis agalactia syndrome (form of postpartum dysgalactiae syndrome, PPDS) caused by susceptible strains of *Escherichia coli.*

In cattle: Therapeutic treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida* and *Mannheimia haemolytica.*

In lactating cows: Treatment of acute mastitis caused by sensitive strains of *Escherichia coli.*

CONTRAINDICATIONS: Do not use in animals with known hypersensitivity to fluoroquinolones or to any of the excipients.

In pigs, to limit development of resistance, do not use fluoroquinolones as prophylaxis or metaphylaxis to prevent diarrhoea at weaning.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties: Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group, which acts by inhibition of DNA gyrase. The in vitro activity of marbofloxacin has been demonstrated towards Pasteurella multocida and Mannheimia haemolytica isolated from bovine respiratory diseases, Escherichia coli isolated from bovine mastitis and Actinobacillus pleuropneumoniae, Pasteurella multocida and E. coli isolated from swine diseases.

Pharmacokinetic particulars: After administration of an intramuscular dose of 8 mg/kg in pigs and 10 mg/kg in cattle, the following mean plasmatic pharmacokinetic parameters were observed:

Parameter	Fattening pigs	Weaned pigs	Sows	Cattle
T_{max}	0.95 h	0.93 h	1 h	1.28 h
C_{max}	6.295 µg/mL	5.550 µg/mL	5.809 µg/mL	7.915 µg/ml
AUC_{INF}	114.7 µg.h/mL	79.89 µg.h/mL	112.0 µg.h/mL	52.7 µg.h/mL
T½lz	15.14 h	13.23 h	11.92 h	17.50 h
F	91.53 %	89.57 %	NC	> 90%

In pigs: Marbofloxacin is extensively distributed. Uterus tissue concentrations in sows reach Cmax of 9.346 µg/g in the uterine body observed at Tmax of 1.00 h after administration and the AUClast was 105.4 µg.h/g.

Binding to plasma proteins is weak, about 4%. In pigs, the elimination is predominantly as the active form in urine and faeces.

Marbofloxacin is eliminated slightly faster in post-weaning piglets than in heavier animals.

In cattle: Marbofloxacin is extensively distributed. Binding to plasma proteins is about 30%.

After intravenous or intramuscular administration, marbofloxacin concentrations in milk increase rapidly and the AUCINF, Tmax and Cmax values obtained in plasma and milk after both administration routes are similar.

Marbofloxacin is eliminated slowly (T½λz = 17.50 h) predominantly as the active form in urine and faeces.

ADVERSE EFFECTS:

In cattle: In very rare cases, administration by the intramuscular route may cause rare transient local reactions such as pain and swelling at the injection site which may persist up to 7 days after injection.

Fluoroquinolones are known to induce arthropathies. In cattle, such lesions were observed after a three days treatment with the 16% marbofloxacin solution. These lesions did not induce clinical signs and should be reversible, particularly if they were to be observed after a single administration.

In very rare cases, anaphylactic-type reactions with a potentially fatal outcome might occur.

In pigs: Local reactions can be observed at the injection site, which disappear within 36 days. Pain at the injection site has been commonly reported.

DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION: To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

Swine: The recommended dosage is 8 mg/kg body weight/day (1 mL/20 kg bw) in a single intramuscular injection in the side of the pig neck.

Cattle: - Therapeutic treatment of respiratory infections 10 mg/kg body weight i.e. 10 mL /160 kg body weight in a single intramuscular injection.

- Treatment of acute mastitis caused by sensitive strains of *Escherichia coli* 10 mg/kg body weight i.e. 10 mL/160 kg body weight in a single intramuscular or intravenous injection.

If the volume to be injected intramuscularly is more than 20 mL, it should be divided between two or more injection sites.

Where there is slight cloudiness or visible particles present, such cloudiness or particles disappear when the bottle is shaken before use.

WITHDRAWAL PERIOD

For swine: Meat and offal: 9 days

For cattle: Meat and offal: 5 days / Milk : 48 hours

SPECIAL STORAGE PRECAUTIONS: Store below 30° C. Protect from moisture.

Shelf-life after first opening the container: 28 days.

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

Keep out of the sight and reach of children.

WARNINGS AND PRECAUTIONS: Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

In cattle, the efficacy of the product has not been tested on mastitis caused by Gram positive bacteria.

i. Special precautions for use in animals: Official and local antimicrobial policies should be taken into account when this product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other class of antimicrobials. Wherever possible, use of the product should only be based on susceptibility testing.

Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals: People with known hypersensitivity to (fluoro)quinolones and benzyl alcohol should avoid any contact with the product.

Wash hands after use. Avoid contact of the skin and eyes with the product. If the product comes into contact with the skin or eyes, rinse with copious amounts of water.

Care should be taken to avoid accidental self-injection. In the event of accidental self-administration, the user should immediately seek professional medical care.

Accidental self-injection can induce a slight irritation.

Use during pregnancy, lactation or lay: Studies in laboratory animals (rats, rabbits) did not show any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin.

The safety of the veterinary medicinal product has not been established at 8 mg/kg in pregnant sows or in suckling piglets when used in sows neither at 10 mg/kg in pregnant cows or in suckling calves when used in cows.