

SUMMARY OF PRODUCT CHARACTERISTICS1. Name of veterinary medicinal product

Marbocyl Bolus

2. Qualitative and quantitative composition

Marbofloxacin	50.00mg
Excipient to	1500mg

3. Pharmaceutical form

Tablet.

4. Pharmacological propertiesPharmacodynamic properties :

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. Fluoroquinolones act by concentration dependant killing mechanism, so high plasma concentration initially is important (see below). It is effective against a wide range of Gram positive bacteria (in particular *Staphylococci*) and Gram negative bacteria (*Escherichia coli*, *Salmonella typhimurium*, *Campylobacter jejunii*, *Citrobacter freundii*, *Enterobacter cloacae*, *Serratia marcescens*, *Morganella morganii*, *Proteus spp*, *Klebsiella spp*, *Shigella spp*, *Actinobacillus pleuropneumonia*, *Bordetella bronchiseptica*, *Pasteurella haemolytica*, *Pasteurella multocida*, *Haemophilus spp*, *Moraxella spp*, *Pseudomonas spp*, *Brucella canis*) as well as Mycoplasma (*Mycoplasma bovis*, *Mycoplasma dispar*, *Mycoplasma hyopneumoniae*).

Pharmacokinetic properties :

After oral administration to calves at the recommended dose of 1mg/kg, marbofloxacin is quite slowly absorbed and its bioavailability is close to 100%. It is weakly bound to plasma proteins (about 30% in calves), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, digestive tract) it achieves higher concentrations than in plasma.

After an oral administration, marbofloxacin is eliminated slowly in calves ($t_{1/2} \beta = 8.50 \pm 2.88h$) predominately in urine (72-81%) and faeces (5-13%) and in active form.

5. Clinical particulars5.1 Target species

Neonatal calves.

5.2 Indications for use, specifying the target species

Marbofloxacin bolus is indicated in the treatment of neonatal gastro-enteritis caused by *Escherichia coli*, in calves of 25-50kg.

5.3 Contra-Indications

None.

5.4 Undesirable effects (frequency and seriousness)

At the recommended dosage, no undesirable effect has to be expected. At twice the dosage, only a reversible, short term decrease of the intestinal *Enterobacteriaceae* population can occur, as well as faecal softening, but without clinical consequence as the balance of aerobes/anaerobes is not affected.

5.5 Special precautions for use

When administration is carried out using an applicator, care should be taken to avoid soft tissue injury.

5.6 Use during pregnancy and lactation

Not relevant.

5.7 Interaction with other medicaments and other forms of interaction

Concurrent administration of oral preparations which contain a high proportion of divalent cations may reduce marbofloxacin activity.

5.8 Posology and method of administration

The recommended dosage is one bolus per calf in a single oral administration per day.

Treatment duration is 3 days.

The bolus can be given manually or with an appropriate applicator.

5.9 Overdose (symptoms, emergency procedures, antidotes)

At four times the recommended dosage, a marked decrease in the intestinal *Enterobacteriaceae* population was observed but this was reversible. At higher dosages, as is known for other oral antibiotics administered to neonatal animals, symptoms in the form of diarrhoea can occur. Further

administration of marbofloxacin must be stopped and the symptoms treated symptomatically.

5.10 Special warnings for the target species

Do not exceed the recommend duration of treatment (3 days).

5.11 Withdrawal periods

Meat : 6 days.

The product is not indicated for use in lactating animals.

5.12 Special precautions to be taken by the person administering the product to animals

None

6. Pharmaceutical particulars

6.1 Incompatibilities

Nil.

6.2 Shelf-life, if necessary after reconstitution of the product, or when the container is opened for the first time

3 years

6.3 Special precautions for storage

Do not store above 25°C.

6.4 Nature and contents of container

Marbocyl Bolus is packaged in thermoshaped blister packs made of orange-yellow polyvinylchloride (PVC) and aluminium.

The product is supplied in a box containing 1, 4, 8, 16, 20, 40, 80 blisters of 6 boluses. Not all pack sizes are marketed.

6.5 Special precautions for the disposal of unused medicinal product or waste materials if any

Any unused product or waste material should be disposed of in accordance with national requirements.

Vétoquinol (UK) Limited

Marbocyl Bolus
Vm 08007/4073

7 Name or style and permanent address or registered place of business of the holder of the authorisation to place the product on the market

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Further Information

Marketing Authorisation Number : VM 08007/4073

Legal category :

POM

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