SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl Bolus 50mg Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

Active substance:
Marbofloxacin 50.00mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.
Off white bolus shaped convex tablet

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (neonatal calves)

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

None

4.4 Special warnings for each target species

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

4.5 Special precautions for use

i. Special precautions for use in animals

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

Official and local antimicrobial policies should be taken into account when the product is used. Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, to other classes of antimicrobials. Whenever possible, fluoroquinolones should

only be used based on susceptibility testing. Use of the product deviating from the instructions given in the SPC 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 fluoroquinolones should avoid using this product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

A greenish coloration of the faeces is sometimes observed, but this is reversible when the treatment is discontinued.

4.7 Use during pregnancy, lactation or lay

Not relevant.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

The recommended dosage is 1mg/kg/day (1 bolus per 50kg calf) in a single oral administration per day.
Treatment duration is 3 days.
The bolus can be given manually or with an appropriate applicator.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

At four times the recommend dosage, a marked, reversible decrease in the intestinal *Enterobacteriaceae* population was observed. Diarrhoea can occur at higher dosages, as is known to occur for other oral antibiotics administered to neonatal animals. Further administration of marbofloxacin must be stopped and symptomatic treatment instituted.

4.11 Withdrawal period(s)

Meat : 6 days.

The product is not indicated for use in lactating animals.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group : Antibacterials for systemic use - fluoroquinolones

ATC Vet Code: QJ01MA93

Pharmacodynamic properties :

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. Fluoroquinolones act by concentration-dependent 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, Cibrobacter freundii, Enterobacter cloacae, Serratia marcescens, Morganella morganii, Proteus spp, Klebsiella spp, Shigella spp, Actinobaillus pleuropneumonia, Bordetella brochiseptica, Pasteurella haemolytica, Pasteurella multocida, Haemophilus spp, Moraxella spp, Pseudomonas spp, Brucella canis*) as well as Mycoplasma (*Mycoplasma bovis, Mycoplasma dispar, Mycoplasma hyopneumoniae).* The bactericidal activity of marbofloxacin is concentration dependant on Gram–negative strains and time dependant on Gram-positive strains.

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 (t½ ß=8.50 ±2.88h) predominately in urine (72-81%) and faeces (5-13%) and in active form.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone K90
Microcrystalline cellulose
Silica colloidal anhydrous
Crospovidone

Hydrogenated castor oil
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4. Special precautions for storage

Do not store above 25°C.

6.4 Nature and composition of immediate packaging

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Vétoquinol UK Limited
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA

Vétoquinol Ireland Ltd
10 Lad Lane
Lower Baggot Street
Dublin 2

8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4073
VPA 10983/35/1

9. DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Ireland: 23 August 1999/23rd August 2009
UK: 5 August 1998/5 August 2008

10. DATE OF REVISION OF THE TEXT

November 2009