SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbonor SOLO 100 mg/ml Solution for Injection for Cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Marbofloxacin	100.0 mg

Excipients:

Monothioglycerol	1.0 mg
Metacresol	2.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow to amber solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

Treatment of respiratory infections caused by susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Histophilus somni*.

4.3 Contraindications

Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross-resistance).

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special Warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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, or are expected to respond poorly, to other classes of antimicrobials. Whenever possible, fluoroquinolones should only be used based upon susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to (flouro)quinolones should avoid any contact with the veterinary medicinal product.
If the product comes into contact with the skin or eyes, rinse with copious amounts of water.
Do not drink, eat or smoke whilst using the veterinary medicinal product.
Wash hands after use.
Accidental self-injection can induce a slight irritation.
In case of accidental self-injection or ingestion, seek medical advice immediately and show package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Fluoroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.
In very rare cases (less than 1 animal in 10,000 animals), the administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which may persist for at least 12 days after injection. No other adverse effects were observed in cattle.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin. Safety of the product at 8 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The recommended dosage is 8 mg/kg bodyweight (2 ml / 25 kg bodyweight) administered as a single intramuscular injection. If the injection volume exceeds 20 ml, it should be divided between two or more injection sites.

The vial may be broached up to 35 times. The user should choose the most appropriate vial size according to the bodyweight of the animal(s) to be treated.

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

No sign of overdosage has been observed after administration of 3 times the recommended dose.
Signs such as neurological disorders may occur when the dose is exceeded. Do not exceed the recommended dose.
Such signs should be treated symptomatically.

4.11 Withdrawal period(s)

Meat and Offal: 3 days
Milk: 72 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, Fluoroquinolones

ATC Vet Code: QJ01MA93

5.1 Pharmacodynamic properties

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group, which acts by inhibition of DNA gyrase. It has a broad-spectrum activity *in vitro* against Gram-positive and Gram-negative bacteria.

The *in vitro* activity of marbofloxacin against pathogens isolated in 2004 from cattle with respiratory diseases during a clinical field trial in France, Germany, Spain and Belgium, was good: MIC values were reported as being between 0.015 and 0.25 µg/ml for *M. haemolytica* (MIC_{90} = 0.124 µg/ml; MIC_{50} = 0.025 µg/ml), between 0.004 and 0.12 µg/ml for *P. multocida* (MIC_{90} = 0.022 µg/ml; MIC_{50} = 0.009 µg/ml) and between 0.015 and 2 µg/ml for *Histophilus somni*. Strains with MIC ≤ 1 µg/ml are sensitive to marbofloxacin whereas strains with MIC ≥ 4 µg/ml are resistant to marbofloxacin.
Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.

5.2 Pharmacokinetic properties

After a single intramuscular administration in cattle at the recommended dose of 8 mg/kg bodyweight, the maximum plasma concentration of marbofloxacin

(Cmax) is 7.3 µg/ml reached in 0.78h (Tmax). The bioavailability of marbofloxacin is almost 100%. Binding to plasma proteins is about 30%. Marbofloxacin is eliminated slowly (T1/2β = 15.60 h), predominantly in the active form in urine and faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monothioglycerol
Metacresol
Disodium Edetate
Gluconolactone
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25^{o}C.
Protect from light.

6.5 Nature and composition of immediate packaging

The product is packaged in 20 ml, 50 ml, 100 ml, 250 ml and 500 ml amber type II glass vials and 60 ml, 100 ml, 250 ml and 500 ml amber co-ex plastic (polypropylene) vials.
The vials are closed with chlorobutyl rubber stoppers sealed with aluminium caps.
Not all pack sizes may be 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 veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Ltd
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4332

9. DATE OF FIRST OF THE AUTHORISATION

26 April 2013

10. DATE OF REVISION OF THE TEXT

January 2018

Approved: 30 January 2018