SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbim 100 mg/ml Solution for Injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Marbofloxacin	100 mg

Excipients:

Metacresol	2.0 mg
Monothioglycerol	1.0 mg
Disodium edetate (E 386)	0.1 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
A clear yellow solution, free of any particulate matter.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and pigs (sows)

4.2 Indications for use, specifying the target species

In Cattle:
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma bovis*.
Treatment of acute mastitis caused by *E. coli* strains sensitive to marbofloxacin during the lactation period.

In Pigs (sows):
Treatment of Metritis Mastitis Agalactia syndrome (postpartum dysgalactia syndrome, PDS) caused by susceptible strains of organisms.

4.3 Contraindications

Do not use for bacterial infections with resistance to other fluoroquinolones (cross resistance).
Do not administer in animals with known hypersensitivity to marbofloxacin or any other quinolone or to any of the excipients.

4.4 Special warnings for each target species

The efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis induced by gram positive bacteria.

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 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.

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

- People with known hypersensitivity to (fluoro) quinolones, or any of the excipients, should avoid contact with the product.
- Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with plenty of clean water.
- Avoid accidental self-injection, since this can cause local irritation. In case of self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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.
However, in cattle, the subcutaneous route was shown to be better tolerated locally than intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle.

4.7 Use during pregnancy, lactation or lay

Pregnancy: Can be used during pregnancy.
Lactation: May be used in lactating cows and sows.
No teratogenic, embryotoxic or maternotoxic effects of marbofloxacin have been shown in experiments with laboratory animals.

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 2 mg/kg/day (1 ml/50 kg) in a single daily injection by intramuscular, subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Treatment durations are 3 days in pigs and 3 to 5 days in cattle.

In order to reduce the risk of particulate contamination of the product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.
The septum should not be punctured more than 35 times.

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

No severe side-effects are to be expected at doses up to 3 or 5 times the recommended dose in cattle and pigs respectively. In particular, no lesions of the articular joints are encountered.
Overdose may cause acute signs in the form of neurological disorders which would have to be treated symptomatically.

4.11 Withdrawal periods

Cattle: Meat and offal: 6 days.
Milk: 36 hours

Pigs: Meat and offal: 4 days.

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 of activity in-vitro against Gram-negative bacteria (including *Pasteurella multocida, Mannheimia haemolytica* and *E. coli,)* and Gram-positive bacteria as well as *Mycoplasma* spp.

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 particulars

After subcutaneous or intramuscular administration in cattle and intramuscular administration in pigs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 µg/ml within less than 1 hour. Its bioavailability is close to 100 %.

It is weakly bound to plasma proteins (less than 10 % in pigs and 30 % in cattle), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, uterus, digestive tract) it achieves a higher concentration than in plasma.

In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves (t½β=5-9h) but faster in ruminant cattle (t½β=4-7h) predominantly in the active form in urine (¾ in pre-ruminating calves, ½ in ruminants) and faeces (¼ in pre-ruminating calves, ½ in ruminants).

In pigs, marbofloxacin is eliminated slowly (t½β=8-10h) predominantly in the active form in urine (⅔) and faeces (⅓).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monothioglycerol
Metacresol
Disodium edetate
Gluconolactone
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
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

Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

The product is presented in amber type II glass vials containing 50 ml and 100 ml. The vials are closed with either chlorobutyl or bromobutyl rubber stopper and oversealed with aluminium caps. Each vial is packaged in an outer carton.

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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4004

9. DATE OF FIRST AUTHORISATION

01 November 2016

10. DATE OF REVISION OF THE TEXT

October 2018

Approved: 18 October 2018