SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocare 20 mg/ml solution for injection for cattle and pigs (UK, IE, FR)
Odimar 20 mg/ml solution for injection for cattle and pigs (BE, NL, LU, ES, PT, DE, AT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Marbofloxacin	20.0 mg

Excipients:

Metacresol	2.0 mg
Monothioglycerol	0.5 mg
Disodium edetate	0.1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear yellowish solution.

4. CLINICAL PARTICULARS

4.1 Target species

- Cattle : pre-ruminants up to 100 kg b.w.
- Pigs

4.2 Indications for use, specifying the target species

Pre-ruminant calves:
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma bovis*.

Pigs:
Treatment of respiratory infections caused by sensitive strains of *Actinobacillus pleuropneumoniae*, *Mycoplasma hyopneumoniae* and *Pasteurella multocida.*

4.3 Contraindications

Do not use in animals with known hypersensitivity to marbofloxacin or to any other quinolone or to any of the excipients.

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

4.4 Special warnings

None.

4.5 Special precautions for use

(i) 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.

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

- People with known hypersensitivity to (fluoro)quinolones should avoid any contact with the product.
- If the product comes into contact with the skin or eyes, rinse with large amounts of water.
- Avoid accidental self-injection, since this can cause local irritation.
- Wash hands after use.
- 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)

Intramuscular or subcutaneous injections are well tolerated although they may cause transitory painful swellings without clinical impact.

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 6 days in pigs and for 12 days in cattle.

4.7 Use during pregnancy, lactation or lay

Marbofloxacin may be used in pregnant and lactating sows.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To ensure administration of the correct dose, body weight should be determined as accurately as possible, to avoid underdosing.

The recommended dosage is 2 mg/kg bodyweight/day (1 ml/ 10 kg BW) in cattle and pigs.

The single daily dose for calves should be administered by subcutaneous or intramuscular injection, for 3-5 days. The first injection may also be given by the intravenous route.

The single daily dose for pigs should be administered by intramuscular injection, for 3-5 days.

The volume of injection should be limited to 10 ml at each site of injection for pigs.

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.

Do not broach the 100mL-vial more than 25 times and a 250mL-vial more than 50 times

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

No severe side-effects are to be expected at doses up to 5 times the recommended dose in cattle and pigs.

Overdosage may cause acute signs in the form of neurological disorders which should be treated symptomatically.

4.11 Withdrawal periods

	MEAT AND OFFAL
Pre-ruminating calves (up to 100kg bodyweight)	6 days
Pigs	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. It acts by inhibition of DNA gyrase and shows concentration dependant bactericidal activity. It has a broad-spectrum activity against Gram-positive bacteria and Gram-negative bacteria (e.g. *Pasteurella multocida*, *Mannheimia haemolytica* and *Actinobacillus pleuropneumoniae*) as well as against mycoplasmas (*Mycoplasma bovis* and *Mycoplasma hyopneumoniae*).
The marbofloxacin *in vitro* activity against pathogens isolated in 2004 from bovine respiratory diseases during a clinical field trial in France, Germany, Spain and Belgium, is good: MIC values are comprised between 0.015 and 0.25 µg/ml for *M. haemolytica* (MIC_{90} = 0.124 µg/ml; MIC_{50} = 0.025 µg/ml) and between 0.004 and 0.12 µg/ml for *P. multocida* (MIC_{90} = 0.022 µg/ml; MIC_{50} =

0.009 µg/ml). Strains with a MIC ≤ 1 µg/ml are sensitive to marbofloxacin whereas strains with a MIC ≥ 4 µg/ml are resistant to marbofloxacin.
Resistance to fluoroquinolones occurs mostly 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 administration in cattle and pigs at the recommended dose of 2 mg/kg body weight, marbofloxacin is readily absorbed and 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 higher concentrations than in plasma.

In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves ($t_{1/2\beta}$ = 5-9 h) predominantly in the active form in urine (3/4) and faeces (1/4).

In pigs, marbofloxacin is eliminated slowly ($t_{1/2\beta}$ = 8-10 h) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Metacresol
Monothioglycerol
Gluconolactone
Mannitol
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: 3 years.
Shelf life after first opening the immediate packaging (20, 50, 100, 250 ml vials): 28 days. The 10mL vials must be used immediately after the first opening.

6.4. Special precautions for storage

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

10 ml vials: Following withdrawal of the required dose, the remainder to the contents of the vial should be discarded.

6.5 Nature and composition of immediate packaging

Packaged in Amber type II glass vials of 10, 20, 50 ml 100 and 250ml.

The vials are closed with a fluorinated bromobutyl rubber stopper and oversealed with an aluminium cap.
Each vial is packaged in a cardboard box.
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

Animalcare Ltd
10 Great North Way
York Business Park
Nether Poppleton
York
YO26 6RB

8. MARKETING AUTHORISATION NUMBER

Vm: 10347/4034

9. DATE OF FIRST AUTHORISATION

Date: 19 December 2012

10 DATE OF REVISION OF THE TEXT

Date: August 2013

21 November 2013