PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON 10 ml, 20 ml, 50 ml, 100 ml and 250 ml sizes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Marbofloxacin 20.0 mg

3. PACKAGE SIZE

10 ml
20 ml
50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle: pre-ruminants up to 100 kg body weight.
Pigs.

5. INDICATIONS

Read the package leaflet before use.

6. ROUTES OF ADMINISTRATION

Cattle: 1 ml/10 kg s.c. or i.m. once daily for 3 to 5 days. The first injection may also be given i.v.
Pigs: 1 ml/10 kg i.m. once daily for 3 to 5 days.

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal period:

	Meat and offal
Pre-ruminating calves (up to 100 kg bodyweight)	6 days
Pigs	4 days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by….
Shelf life after first opening the immediate packaging:

(20 ml, 50 ml, 100 ml, 250 ml): 28 days.

Shelf life after first opening the immediate packaging (10 ml): use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

10 ml vials: Vial must be used immediately after opening. Following withdrawal of the required dose, the remaining contents of the vial should be discarded.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

14. MARKETING AUTHORISATION NUMBERS

Vm 34534/3006
Vm 34534/5013

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE { 100 ml and 250 ml sizes }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Marbofloxacin 20.0 mg

3. TARGET SPECIES

Cattle: pre-ruminants up to 100 kg body weight.
Pigs.

4. ROUTES OF ADMINISTRATION

Cattle: **s.c.**, **i.m.** or **i.v.**
Pigs: **i.m.**

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

	Meat and offal
Pre-ruminating calves (up to 100 kg bodyweight)	6 days
Pigs	4 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by….
Shelf life after first opening the immediate packaging: 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {10 ml, 20 ml and 50 ml vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 20 mg/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Marbofloxacin 20.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use by…

Shelf life after first opening the immediate packaging (20 ml, 50ml): 28 days.

Shelf life after first opening the immediate packaging (10 ml): use immediately

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Marbodug 20 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml contains:

Active substance: Marbofloxacin 20.0 mg

Excipients:
Metacresol 2.0 mg
Monothioglycerol 0.5 mg
Disodium edetate 0.1 mg

Clear yellowish solution.

3. Target species

Cattle: (pre-ruminants up to 100 kg bodyweight) and pigs.

4. Indications for use

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*

5. Contraindications

Do not use in cases of hypersensitivity to the active substance 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).

Do not use in case of disturbance in growth of cartilage and/or during injury of the locomotion system particularly on functionally loaded joints.

6. Special warnings

Special precautions for safe use in the target species:

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 veterinary medicinal product to animals:

People with known hypersensitivity to (fluoro)quinolones should avoid any contact with the veterinary medicinal product.
If the veterinary medicinal 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.

Pregnancy and lactation:

Marbofloxacin may be used in pregnant and lactating sows.

Overdose:

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.

Major incompatibilities:

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

7. Adverse events

Cattle (Pre-ruminant up to 100 kg b.w. calves), pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Skin swelling[1] Injection site reactions[2] (e.g. injection site pain, injection site swelling, injection site inflammation, injection site lesion)[2]

[1]Transient painful swellings without clinical impact following intramuscular or subcutaneous injection.

[2] May persist for 6 days in pigs and 12 days in cattle after intramuscular injection.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Pigs: Intramuscular use (**i.m.**).
Cattle: Subcutaneous use (**s.c.**), Intramuscular use (**i.m.**) or Intravenous use (**i.v.**).

To ensure a correct dosage, body weight should be determined as accurately as possible.

The recommended dosage is 2 mg/kg body weight/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.

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

9. Advice on correct administration

In order to reduce the risk of particulate contamination of the veterinary medicinal product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.

10. Withdrawal periods

Withdrawal period:

	Meat and offal
Pre-ruminating calves (up to 100kg bodyweight)	6 days
Pigs	4 days

11. Special storage precautions

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging (20, 50, 100, 250 ml vials): 28 days.

Shelf life after first opening the immediate packaging (10 ml): use immediately.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton/label.

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

This veterinary medicinal product does not require any special temperature storage conditions.

For the 10 ml vial only:

Vial must be used immediately after opening. Following withdrawal of the required dose, the remaining contents of the vial should be discarded.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof by local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 34534/3006
Vm 34534/5013

Packaged in Amber Type II glass vials of 10, 20, 50, 100 and 250 ml.
Not all pack sizes may be marketed.

15. PID link (Do not print heading)

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Emdoka, John Lijsenstraat 16, B-2321 Hoogstraten, Belgium

+32 (0) 3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:

Produlab Pharma B.V., Forellenweg 16, 4961 SJ Raamsdonksveer, Netherlands

17. Other information

POM-V

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.

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 hours) 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 hours) predominantly in the active form in urine (2/3) and faeces (1/3).

Gavin Hall

Approved: 19 January 2025