LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON (10, 20 and 50ml sizes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Marbofloxacin 20.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml
50 ml

5. TARGET SPECIES

Cattle: pre-ruminants up to 100 kg bodyweight.
Pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: 1 ml/10 kg SC or IM once daily for 3 to 5 days. The first injection may also be given IV.
Pigs: 1 ml/10 kg IM once daily for 3 to 5 days.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: DD/MM/YYYY
Once broached, use by…
Shelf-life after first opening the immediate packaging: 28 days.

For the 10 ml vial only:
Vial must be used immediately after opening.

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten

Belgium

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 34534/4010

IE: VPA 10534/006/001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON (100 and 250ml sizes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Marbofloxacin 20.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle: pre-ruminants up to 100 kg bodyweight.
Pigs

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: 1 ml/10 kg SC or IM once daily for 3 to 5 days. The first injection may also be given IV.
Pigs: 1 ml/10 kg IM once daily for 3 to 5 days.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: DD/MM/YYYY
Once broached, use by…
Shelf-life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 34534/4010

IE: VPA 10534/006/001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10, 20 and 50ml VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 20 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Marbofloxacin 20 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC, IM or IV
Pigs: IM

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

EXP: DD/MM/YYYY
Once broached, use by…

For the 10 ml vial only:
Vial must be used immediately after opening.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml Vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Marbofloxacin 20.0 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

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

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: SC, IM or IV
Pigs: IM

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

	Meat and offal
Pre-ruminating calves (up	6 days

to 100kg bodyweight)	
Pigs	4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by…
Shelf-life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 34534/4010

IE: VPA 10534/006/001

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Marbodug 20 mg/ml Solution for Injection for Cattle and Pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

Manufacturer for the batch release:
Produlab Pharma B.V.
Forellenweg 16
4961 SJ Raamsdonksveer
Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 20 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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 for injection.

4. INDICATION(S)

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 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).

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. ADVERSE REACTIONS

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

Administration by the intramuscular route *very rarely* 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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Cattle: pre-ruminants up to 100 kg bodyweight
Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. 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.

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.
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 WARNING(S)

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 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.

Use during pregnancy or lactation

Marbofloxacin may be used in pregnant and lactating sows.

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.

Major Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

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.

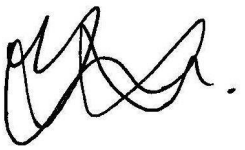
Pharmacokinetic particulars

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).

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



Approved: 01 December 2020