LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON (10, 20 and 50 ml sizes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 100 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Marbofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

10 ml
20 ml
50 ml

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: 1 ml/50kg IM, SC or IV once daily for 3 to 5 days OR alternatively one single IM injection of 2 ml/25kg when treating respiratory infections
Pigs: 1 ml/50kg IM once daily for 3 days.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

	Meat and offal	**Milk**

Cattle 2mg/kg for 3 to 5 days **(**IV/IM/SC)	6 days	36 hours
Cattle 8mg/kg on a single occasion (IM)	3 days	72 hours
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 34534/4009

IE: VPA 10534/006/002

17. MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON (100 and 250 ml sizes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 100 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Marbofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100mL
250mL

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: 1 ml/50kg IM, SC or IV once daily for 3 to 5 days OR alternatively one single IM injection of 2 ml/25kg when treating respiratory infections
Pigs: 1 ml/50kg IM once daily for 3 days.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

	Meat and offal	Milk
Cattle 2mg/kg for 3 to 5 days **(**IV/IM/SC)	6 days	36 hours
Cattle 8mg/kg on a single occasion (IM)	3 days	72 hours
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 34534/4009

IE: VPA 10534/006/002

17. MANUFACTURER'S BATCH NUMBER

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10, 20 and 50ml VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 100 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Marbofloxacin 100 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	**Milk**
Cattle 2mg/kg for 3 to 5 days **(**IV/IM/SC)	6 days	36 hours
Cattle 8mg/kg on a single occasion (IM)	3 days	72 hours
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

100ml AND 250ml VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbodug 100 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Marbofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250ml

5. TARGET SPECIES

Cattle and 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	**Milk**

Cattle 2mg/kg for 3 to 5 days **(**IV/IM/SC)	6 days	36 hours
Cattle 8mg/kg on a single occasion (IM)	3 days	72 hours
Pigs	4 days	

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached,/opened, 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 34534/4009

IE: VPA 10534/006/002

17. MANUFACTURER'S BATCH NUMBER

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Marbodug 100 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 100 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 100.0 mg

Excipients:
Metacresol 2.0 mg
Monothioglycerol 1.0 mg
Disodium edetate 0.1 mg

Clear, yellowish solution for injection.

4. INDICATION(S)

In cattle:
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica, Histophilus somni* and *Mycoplasma bovis*.

Treatment of acute mastitis caused by *E.coli* strains sensitive to marbofloxacin during the lactation period.

In pigs:
Treatment of Metritis Mastitis Agalactia syndrome (postpartum dysgalactiae syndrome, PDS) caused by susceptible strains of organisms.

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).

6. ADVERSE REACTIONS

Intramuscular or subcutaneous injections are well tolerated although *very rarely* transitory inflammatory lesions without clinical impact can occur at the injection site.

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 at least 12 days after injection. No other adverse effect was observed on cattle.

If you notice any serious effects or other effects not mentioned in this 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 displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

7. TARGET SPECIES

Cattle and 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.

Cattle:
Respiratory infections:
This product may be administered as a single dose given on one day only or as a multiple dose injection given over 3-5 days.

Single dose – Intramuscular use:
The recommended dosage is 8 mg/kg bodyweight (i.e. 2 ml of product /25 kg bodyweight in a single injection). This optimised dosing regimen should be considered as the dosing regimen of choice in the treatment of cattle respiratory disease with the exception of the situations listed below.

Multiple dose – Intramuscular, intravenous or subcutaneous use:
The recommended dosage is 2mg/kg bodyweight (i.e. 1 ml of product /50 kg bodyweight in a single daily injection for 3-5 days). This dosing regimen should be used for treatment of specific cases such as those which require intravenous treatment or infections caused by *Mycoplasma bovis*).

Acute mastitis:
- Intramuscular or subcutaneous use:
The recommended dosage is 2 mg/kg bodyweight (i.e. 1 ml of product/ 50 kg bodyweight in a single daily injection, for 3 consecutive days.
The first injection may also be given by the intravenous route.

Pigs (sows):
-Intramuscular use:
The recommended dosage is 2 mg/kg bodyweight (i.e. 1 ml of product/ 50 kg bodyweight in a single daily injection, for 3 consecutive days).

9. ADVICE ON CORRECT ADMINISTRATION

If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.

It is preferable to inject cattle and pigs in the neck.

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

10. WITHDRAWAL PERIOD

	Meat and offal	Milk
Cattle 2mg/kg for 3 to 5 days **(**IV/IM/SC)	6 days	36 hours
Cattle 8mg/kg on a single occasion (IM)	3 days	72 hours
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, 250ml 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 warnings for each target species
Efficacy data have shown an insufficient efficacy of the product for the treatment of acute mastitis caused by Gram positive strains.

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
Laboratory studies in the rat and rabbit have not produced any evidence of a teratogenic, foetoxic or maternotoxic effect.

Dose of 2 mg/kg body weight:
The safety of the product has been established in pregnant and lactating cows and sows

Dose of 8 mg/kg body weight:
The safety of the veterinary medicinal product has not been established in the pregnant cow or in suckling calves when used in the cow. Therefore, in pregnant and lactating animals this dose regimen should be used only according to the benefit/risk assessment by the responsible veterinarian.

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.
Overdosage may cause acute signs in the form of neurological disorders which would have to 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 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.

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

June 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*, *Histophilus somni*, *E. coli*) as well as against mycoplasmas (*Mycoplasma bovis*).

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* (MIC90 = 0.124 µg/ml; MIC50 = 0.025 µg/ml), between 0.004 and 0.12 µg/ml for *P. multocida* (MIC90 = 0.022 µg/ml; MIC50 = 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 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.

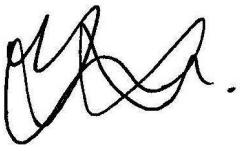
Pharmacokinetic particulars

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

After a single intramuscular administration in cattle at the recommended dose of 8 mg/kg body weight, the maximum plasma concentration of marbofloxacin (Cmax) is 7.3 µg/ml reached in = 0.78h (Tmax). Binding to plasma proteins is about 30%. Marbofloxacin is eliminated slowly (t½ β = 15.60 h), predominantly in the active form in urine and faeces.

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 (t½ β = 5-9h) but faster in ruminant cattle (t½ β = 4-7h) predominantly in the active form in urine (3/4 in pre-ruminating calves, 1/2 in ruminants) and faeces (1/4 in pre-ruminating calves, 1/2 in ruminants).
In pigs, marbofloxacin is eliminated slowly (t½ β = 8-10h) 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