

Barrows

A. LABELLING

Arrows

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbosol 100 mg/ml solution for injection for cattle and pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin 100 mg/ml

Excipients:

Metacresol 2 mg

Monothioglycerol 1 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

100 ml

5. TARGET SPECIES

Cattle, Pigs

6. INDICATION(S)

Cattle:

Treatment of respiratory infections caused by susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni*.

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

Pigs:

Treatment of Metritis Mastitis Agalactia Syndrome (MMA Syndrome, postpartum dysgalactia syndrome, PDS) caused by bacterial strains susceptible to marbofloxacin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: IM, SC and IV (only the first injection) use.

Pigs: IM use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:

Arrows

Single dose (8 mg/kg) (IM)

Meat and offal: 3 days

Milk: 72 hours

Multiple dose (2 mg/kg single daily injection, for 3 to 5 days) (IV/SC/IM)

Meat and offal: 6 days

Milk: 36 hours

Pigs:

Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

In case of contact with the skin or eyes, rinse with large amounts of water.

Read the package leaflet before use.

10. EXPIRY DATE

EXP: <month/year>

Shelf-life after first opening the immediate packaging: 28 days.

Once broached, use by....

11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use.

12. SPECIFIC 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.

<National issue: IE: POM>

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH
Ostlandring 13
31303 Burgdorf
Germany

Arrows

16. MARKETING AUTHORISATION NUMBER(S)
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<to be completed nationally>

<IE: 10810/010/002>

17. MANUFACTURER'S BATCH NUMBER
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Batch: <number>

Arrows

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbosol 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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: IM, SC, IV
Pigs: IM

5. WITHDRAWAL PERIOD

Cattle:
Single dose (8 mg/kg) (IM)
Meat and offal: 3 days
Milk: 72 hours

Multiple dose (2 mg/kg single daily injection, for 3 to 5 days) (IV/SC/IM)
Meat and offal: 6 days
Milk: 36 hours

Pigs:
Meat and offal: 4 days

6. BATCH NUMBER

Batch: <number>

7. EXPIRY DATE

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

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
<National issue: IE: POM>

Arrows

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbosol 100 mg/ml solution for injection for cattle and pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per ml:

Active substance:

Marbofloxacin 100 mg/ml

Excipients:

Metacresol 2 mg

Monothioglycerol 1 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: IM, SC or IV use

Pigs: IM use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:

Single dose (8 mg/kg) (IM)

Meat and offal: 3 days

Milk: 72 hours

Arrows

Multiple dose (2 mg/kg single daily injection, for 3 to 5 days) (IV/SC/IM)
Meat and offal: 6 days
Milk: 36 hours

Pigs:
Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

In case of contact with the skin or eyes, rinse with large amounts of water.
Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use.

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

For animal treatment only

<National issue: IE: POM>

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER’S BATCH NUMBER

Arrows

Batch {number}

Barrows

B. PACKAGE LEAFLET

Arrows

PACKAGE LEAFLET

Marbosol 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

CP-Pharma Handelsges. mbH
Ostlandring 13
31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbosol 100 mg/ml solution for injection for cattle and pigs
Marbofloxacin

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

Per ml:

Active substance:

Marbofloxacin: 100 mg

Excipients:

Preservative:

Metacresol 2 mg

Monothioglycerol 1 mg

Clear, yellow solution.

4. INDICATION(S)

Cattle:

Treatment of respiratory infections caused by susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni*.

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

Pigs:

Treatment of Metritis Mastitis Agalactia Syndrome (MMA Syndrome, postpartum dysgalactia syndrome, PDS) caused by bacterial strains susceptible to marbofloxacin.

5. CONTRAINDICATIONS

Arrows

Do not use in case of bacterial infections with resistance to other fluoroquinolones (cross resistance).

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Fluoroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.

Intramuscular administration may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which persist, at least, 12 days after injection.

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

7. TARGET SPECIES

Cattle, pigs

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

Cattle:

Single dose (8 mg/kg) treatment of respiratory infections:

The recommended dosage is 8 mg/kg bodyweight/day (2 ml/25 kg BW) in a single intramuscular injection.

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

Multiple dose (2 mg/kg single daily injection, for 3 to 5 days) treatment of acute mastitis:

The recommended dosage is 2mg/kg bodyweight/day (1ml/50kg BW) in a single daily injection by intramuscular, subcutaneous or intravenous (only the first injection) routes, for 3 - 5 consecutive days.

Pigs:

The recommended dosage is 2 mg/kg bodyweight/day (1ml/50kg BW) in a single daily injection by intramuscular route, for 3 consecutive days.

In cattle and pigs, the preferred site of injection is the neck.

To ensure a correct dose body weight should be determined as accurately as possible to avoid underdosing.

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.

The stopper should not be punctured more than 20 times, the user should choose the most appropriate vial size according to the target species to treat.

9. ADVICE ON CORRECT ADMINISTRATION



Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD

Cattle:

Single dose (8 mg/kg) (IM)

Meat and offal: 3 days

Milk: 72 hours

Multiple dose (2 mg/kg single daily injection, for 3 to 5 days) (IV/SC/IM)

Meat and offal: 6 days

Milk: 36 hours

Pigs:

Meat and offal: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

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

Shelf-life after first opening the bottle: 28 days.

Do not use after the expiry date stated on the carton and bottle after EXP.

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

When the container is breached (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 label.

12. SPECIAL WARNING(S)

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.

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.

User warnings

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

This medicine is associated with sensitization and contact dermatitis and therefore direct contact with skin should be avoided.

In case of contact with the skin or eyes, rinse with large amounts of water.

Arrows

Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

Use during pregnancy and lactation

Studies in laboratory animals (rats, rabbits) did not show any evidence of a teratogenic embryotoxic or maternotoxic effect associated with the use of marbofloxacin. Safety of the product has not been determined in pregnant and lactating cows and sows. Use therefore according to the benefit/risk assessment carried out by the responsible veterinarian.

Interactions

Fluoroquinolones may increase concentrations of theophylline if used concurrently. Coadministration with divalent and trivalent cations, such as products containing aluminium (e.g. sucralfate), iron, and calcium, may decrease absorption. Do not mix in solution or in vials with albumin, calcium, iron, or zinc because chelation may occur. Marbofloxacin may be administered with other antibiotics and anaesthetic agents without evidence of drug interaction.

Overdose

No signs of overdosage have been observed after administration of up to 3 times the recommended dose in cattle and up to 5 times in pigs.

Signs such as neurological disorders may occur when the dose is exceeded. Such signs should be treated symptomatically.

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 product should be disposed of in accordance with local requirements.

Medicines should not be disposed of via wastewater or household waste but 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

To be completed nationally

15. OTHER INFORMATION

50 ml amber type II glass bottle with a chlorobutyl rubber stopper and an aluminium cap.

100 ml amber type II glass bottle with a chlorobutyl rubber stopper and an aluminium cap.

Not all pack sizes may be marketed.

MA number:

<to be established nationally>

Arrows

<IE: 10810/010/002>

<National issue:
IE: POM – Prescription Only Medicine>