A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbosol 20 mg/ml solution for injection for calves and piglets
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:
Marbofloxacin 20 mg

Excipients:
Metacresol 2 mg
Monothioglycerol 0.50 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Pre-ruminating calves, piglets

6. INDICATION(S)

Pre-ruminating calves:
For treatment and prevention of respiratory infections caused by marbofloxacin susceptible *Mannheimia haemolytica* and *Pasteurella multocida* strains, where the presence of the disease has been established in the group.

Piglets:
For the treatment of respiratory infections caused by marbofloxacin susceptible *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae* and *Pasteurella multocida* strains.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Calves: IM, SC or IV (for the first administration only) use
Piglets: IM use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal:
Calves: 6 days
Piglets: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

In case of contact with the skin or eyes, rinse with large amount 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

16. MARKETING AUTHORISATION NUMBER(S)

<to be completed nationally>

<IE: 10810/010/001>

17. MANUFACTURER'S BATCH NUMBER

Batch: <number>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbosol 20 mg/ml solution for injection for calves and piglets
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Marbofloxacin 20 mg/ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Calves: IM, SC, IV
Piglets: IM

5. WITHDRAWAL PERIOD

Meat and offal:
Calves: 6 days
Piglets: 3 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>

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbosol 20 mg/ml solution for injection for calves and piglets
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per ml:
Active substance:
Marbofloxacin 20 mg/ml

Excipients:
Metacresol 2 mg
Monothioglycerol 0.50 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle (pre-ruminating calves), piglets

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Calves: IM, SC or IV (for the first administration only) use
Piglets: IM use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal:
Calves: 6 days
Piglets: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

In case of contact with the skin or eyes, rinse with large amount 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: 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

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Marbosol 20 mg/ml solution for injection for calves and piglets

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 20 mg/ml solution for injection for calves and piglets

Marbofloxacin

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

Per ml:

Active substance:
Marbofloxacin: 20 mg

Excipients:
Metacresol 2 mg
Monothioglycerol 0.50 mg

Clear, yellow solution.

4. INDICATION(S)

Pre-ruminating calves:
For treatment and prevention of respiratory infections caused by marbofloxacin susceptible *Mannheimia haemolytica* and *Pasteurella multocida* strains, where the presence of the disease has been established in the group.

Piglets:
For the treatment of respiratory infections caused by marbofloxacin susceptible *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae* and *Pasteurella multocida* strains.

5. CONTRAINDICATIONS

Do not use in case of bacterial infections with resistance to other (fluoro)quinolones (cross resistance).
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Administration may cause a painful swelling at the injection site that disappears after a few days. Inflammatory lesions can persist 6 days in piglets and 12 days in calves.

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

7. TARGET SPECIES

Cattle (pre-ruminating calves), piglets

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

Pre-ruminating calves:
Intramuscular, subcutaneous or intravenous (for the first administration only) use:
2 mg/kg bodyweight/day (1 ml/10 kg BW/day) for 3 – 5 days.

Piglets:
Intramuscular use:
2 mg/kg bodyweight/day (1 ml/10 kg BW/day) for 3 – 5 days.

Do not inject the product in the same place in neck area. Maximal injection volume per injection should not exceed 5.5 ml for calves and 3.0 ml for pigs.
To ensure a correct dose body weight should be determined as accurately as possible to avoid underdosing. 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

Meat and offal:
Pre-ruminating calves: 6 days
Piglets: 3 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 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 label.

12. SPECIAL WARNING(S)

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 contact with the veterinary medicinal product.
This medicine is associated with sensitization and contact dermatitis and therefore direct contact with the skin should be avoided.
In case of contact with the skin or eyes, rinse with large amounts of water.
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
Not applicable.

Interactions
No NSAIDs may be given, except for tolfenamic acid, simultaneously or within 24 hours after each administration.

Fluoroquinolones may increase concentrations of theophyline 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 calves 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.
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>
<IE: 10810/010/001>

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