LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes of 50, 100, 250 and 500 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 100 mg of marbofloxacin

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml
500 ml

5. TARGET SPECIES

Catte and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: intramuscular, subcutaneous or intravenous
Pigs: intramuscular
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:
Intramuscular: Meat and offal: 3 days - Milk: 72 hours
Subcutaneous**:** Meat and offal: 6 days - Milk: 36 hours

Sows:
Intramuscular: Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP:
Once opened, use within 28 days by: ___/___/___

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 package leaflet.

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

For animal treatment - To be supplied only on veterinary prescription

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4048

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: IM, SC or IV
Sows: IM

5. WITHDRAWAL PERIOD

Cattle:
IM: Meat and offal: 3 days - Milk: 72 hours
SC**:** Meat and offal: 6 days - Milk: 36 hours

Sows:
IM: Meat and offal: 4 days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Once opened, use within 28 days by: ___/___/___

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial labels of 100, 250 and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 100 mg of marbofloxacin

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml
250 ml
500 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: IM, SC or IV
Sows: IM.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:
IM: Meat and offal: 3 days - Milk : 72 hours
SC**:** Meat and offal: 6 days - Milk: 36 hours

Sows:
IV: Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP:
Once opened, use within 28 days, by: ___/___/___

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

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

For animal treatment - To be supplied only on veterinary prescription

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4048

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR
Marbox 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:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale, 10 av. de la La Ballastière, 33500 Libourne, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbox 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

Clear, yellow solution.

4. INDICATION(S)

Cattle:
Therapeutic treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni*.
Therapeutic treatment of acute mastitis caused by *E. coli* strains sensitive to marbofloxacin during the lactation period.

Sows:
Treatment of Metritis Mastitis Agalactiae Syndrome caused by bacterial strains sensitive to marbofloxacin.

5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to the active substance or other (fuoro)quinolones or to any of the excipients.
Do not use in case of confirmed or suspected resistance to fluoroquinolones (cross resistance).

6. ADVERSE REACTIONS

Administration by the intramuscular route may cause in cattle transient local reactions such as pain at the injection site and slight muscular inflammatory lesions (resulting in fibrosis). The process of cicatrisation starts rapidly (varying from fibrosis to synthesis of extracellular matrice and collagen) and may persist for at least 15 days after injection.

Administration by the subcutaneous route may induce slight to moderate oedema at the injection site. A moderate pain on palpation of the injection site occurred in some animals.

In pigs, administration by the intramuscular route may induce very transient slight oedema and mild inflammatory lesions at the injection site persisting for 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 and pigs (sows).

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

Cattle:
Intramuscular use:
- *Respiratory infections:*
The recommended dosage is 8 mg/kg bodyweight i.e. 2 ml/25 kg bodyweight in a single injection.
If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.

Subcutaneous use:
- *Acute mastitis:*
The recommended dosage is 2 mg/kg i.e. 1 ml/50 kg bodyweight in a single daily injection, for 3 days.
The first injection may also be given by the intravenous route too.

Sows:
Intramuscular use:
The recommended dosage is 2 mg/kg i.e.1 ml/50kg bodyweight in a single daily injection by intramuscular route, for 3 days.

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Cattle:
Intramuscular: Meat and offal: 3 days - Milk : 72 hours
Subcutaneous**:** Meat and offal: 6 days - Milk: 36 hours

Sows:
Intramuscular: Meat and offal: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the container in the outer carton in order to protect from light.
Do not use after the expiry date stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Use of the product should be based on susceptibility testing and has to take into account official and local antimicrobial policies.
It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antibiotics.
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.
As the vial cannot be broached more than 45 times, the user should choose the most appropriate vial size according to the target species to treat.
For the injections, the neck should be preferred in cattle and pigs.

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 copious amounts of water.
Take care to avoid accidental self injection since it can induce a slight irritation.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician.
Wash hands after use.

Use during pregnancy, lactation or lay
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 at 2 mg/kg has been shown in cows during gestation and in suckling pigs and calves when used in sows and cows.
Safety of the product at 8 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Use therefore according to the benefit/risk assessment carried out by the responsible veterinarian.

Overdose (symptonms, emergency procedures, antidotes)
No sign of overdosage has been observed in cattle after administration of 3 times the recommended dose.
Overdosage may cause signs such as acute neurological disorders which 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.

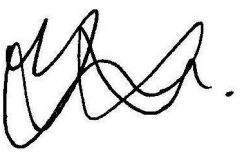
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Pack size
Cardboard box containing one 50 ml vial
Cardboard box containing one 100 ml vial
Cardboard box containing one 250 ml vial
Cardboard box containing one 500 ml vial

Not all pack sizes may be marketed.



Approved: 14 October 2022