

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbox 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 100 mg of marbofloxacin

3. PACKAGE SIZE

50 ml
100 ml
250 ml
500 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Cattle: intramuscular, subcutaneous or intravenous

Pigs: intramuscular

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp: {mm/yyyy}

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

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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

Keep out of the sight and reach of children

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5043

Vm 14966/3042

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

(100 ml, 250 ml and 500 ml labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbox 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 100 mg of marbofloxacin

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Cattle: IM, SC or IV

Sows: IM

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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. EXPIRY DATE

Exp: {mm/yyyy}

Once opened, use within 28 days by: ____/____/____

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE

50 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbox

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

100 mg of marbofloxacin per ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp: {mm/yyyy}

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

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Marbox 100 mg/ml Solution for Injection for Cattle and Pigs

2. Composition

Each ml contains:

Active substance:

Marbofloxacin.....100 mg

Clear, yellow solution.

3. Target species

Cattle and pigs (sows)

4. Indications for use

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 (fluoro)quinolones or to any of the excipients.

Do not use in case of confirmed or suspected resistance to fluoroquinolones (cross resistance).

6. Special warnings

Special precautions for safe use in the target species:

Use of the veterinary medicinal 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 veterinary medicinal product.

If the veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable

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 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.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

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

7. Adverse events

Cattle:

Undetermined frequency	Injection site pain ^{1,2} Injection site inflammation ¹ Injection site fibrosis ¹ Injection site oedema ²
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¹The 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.

² After subcutaneous injection

Pigs (sows):

Undetermined frequency	Injection site inflammation ¹ Injection site oedema ¹
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¹ Very transient, slight

² persisting for 12 days after injection

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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.

9. Advice on correct administration

10. Withdrawal periods

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 precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5043

Vm 14966/3042

Pack sizes

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing Authorisation Holder:

Ceva Sante Animale

8 rue de Logrono

33500 Libourne

France

Contact details to report suspected adverse reactions:

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

Tel. 01628 334056
email technicalandpvuk-group@ceva.com

Manufacturer responsible for batch release:

Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

17. Other information

POM-V

Veterinary Medicinal product subject to prescription
For animal treatment only

Gavin Hall
Approved: 07 January 2026