LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard boxes of 50, 100, 250 and 500 ml vials

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE Vials of 100, 250 and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOKEM 100 mg/ml solution for injection [AT, BE, BG, CY, CZ, DK, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SK, UK]
MARBOKEM 100 mg/ml solution for injection for cattle [DE]
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
100 mg marbofloxacin

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

50 ml
100 ml
250 ml
500 ml

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use and disposal.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 3 days
Milk: 72 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use and disposal.

10. EXPIRY DATE

EXP:
Shelf-life after first broaching the vial: 28 days.
Once broached, use 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

Read the package leaflet before use and disposal.

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

To be supplied only on veterinary prescription.
For animal treatment only

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOKEM 100 mg/ml solution for injection [AT, BE, BG, CY, CZ, DK, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SK, UK]
MARBOKEM 100 mg/ml solution for injection for cattle [DE]
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.
I.M.
Read the package leaflet before use and disposal.

5. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 3 days
Milk: 72 hours

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Shelf-life after first broaching the vial: 28 days.
Once broached, use by ___/___/___
Protect from light.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY.
To be supplied only on veterinary prescription. [UK]

Revised: February 2012 – change of UK MAH address

B. PACKAGE LEAFLET

PACKAGE LEAFLET
MARBOKEM 100 mg/ml solution for injection
Marbofloxacin

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, Unit 3, Anglo Office Park, White Lion Road, Amersham, Bucks, HP7 9FB

Manufacturer for the batch release:
CEVA SANTE ANIMALE – 10 avenue de la Ballastière – 33500 Libourne - FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOKEM 100 mg/ml solution for injection [AT, BE, BG, CY, CZ, DK, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SK, UK]
MARBOKEM 100 mg/ml solution for injection for cattle [DE]
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)

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

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to fluoroquinolones.
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

6. ADVERSE REACTIONS

Fluoroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.
Administration by the intramuscular route may cause 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 matrix and collagen) and may persist for at least 15 days after injection.
No other adverse injection site effects have been observed in cattle.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

Intramuscular use (I.M.).
The recommended dosage is 8 mg/kg bodyweight i.e. 2 ml/25 kg bodyweight in a single intramuscular injection.

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.

10. WITHDRAWAL PERIOD

Meat and offal: 3 days
Milk: 72 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton in order to protect from light.
Do not use after the expiry date stated on the label and carton after EXP.
Shelf-life after first broaching the vial: 28 days.

Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

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 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.
Accidental self-injection can induce a slight irritation.

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 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
No sign of overdosage has been observed 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 product or waste materials should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2009

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.