PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actimarbo 100 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin 100 mg/ml
Metacresol 2 mg/ml, Monothioglycerol 1 mg/ml, Disodium edetate 0.1 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 vial of 20 ml
1 vial of 50 ml
1 vial of 100 ml

5. TARGET SPECIES

Cattle & pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular / subcutaneous / intravenous.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:

- IM (8 mg/kg single dose)
  Meat and offal: 3 days
  Milk: 72 hours
- IM or SC (2 mg/kg single daily injection for 3 to 5 days)
  Meat and offal: 6 days
  Milk: 36 hours

Pigs (sows):

- IM

  Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use for full instructions and user warnings.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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.

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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp, Belgium

16. MARKETING AUTHORISATION NUMBER(S)

...

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actimarbo 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

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

IM / SC / IV

5. WITHDRAWAL PERIOD

Cattle:

- IM (8 mg/kg single dose)
  Meat and offal: 3 days
  Milk: 72 hours
- IM or SC (2 mg/kg single daily injection for 3 to 5 days)
  Meat and offal: 6 days
  Milk: 36 hours

Pigs (sows):

- IM
  Meat and offal: 4 days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actimarbo 100 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin 100 mg/ml
Metacresol 2 mg/ml, Monothioglycerol 1 mg/ml, Disodium edetate 0.1 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle & pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM / SC / IV

8. WITHDRAWAL PERIOD

Cattle:

- IM (8 mg/kg single dose)
  Meat and offal: 3 days
  Milk: 72 hours
- IM or SC (2 mg/kg single daily injection for 3 to 5 days)
  Meat and offal: 6 days
  Milk: 36 hours

Pigs (sows):

- IM
  Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use for full instructions and user warnings.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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.

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

Ecuphar NV

16. MARKETING AUTHORISATION NUMBER(S)

...

17. MANUFACTURER'S BATCH NUMBER

Lot

PACKAGE LEAFLET

Actimarbo 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:

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

or

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
HA1 4HF Middlesex
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actimarbo 100 mg/ml Solution for Injection for Cattle and Pigs
Marbofloxacin

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

Each ml:

Active substance:
Marbofloxacin 100 mg

Excipients:

Metacresol	2 mg
Monothioglycerol	1 mg
Disodium edetate (E 386)	0.1 mg

The product is a clear pale yellow to greenish–brownish yellow aqueous solution.

4. INDICATION(S)

In 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.

In pigs:
Treatment of Metritis Mastitis Agalactia syndrome caused by susceptible strains of organisms.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to marbofloxacin or any quinolones; or to any of the excipients.
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

6. ADVERSE REACTIONS

No severe side-effects are to be expected at doses up to 3 or 5 times the recommended dose in cattle and pigs respectively.
Transitory inflammatory lesions without clinical impact can occur at the injection site after intramuscular or subcutaneous injections. Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions, which may persist, for at least 12 days after injection. However, in cattle, subcutaneous route was shown to be better tolerated locally than intramuscular route.

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

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible to avoid underdosing.

Cattle:
Respiratory infections:
- Intramuscular use:

The recommended dosage is 8 mg / kg body weight i.e. 2 ml / 25 kg body weight 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.

Acute mastitis:

- Intramuscular or subcutaneous use:

The recommended dosage is 2 mg / kg / day (1 ml / 50 kg) in a single daily injection.

Treatment duration is 3 to 5 days. The first injection may also be given by the intravenous route too. The subcutaneous route is recommended in heavy cattle (see section “Adverse reactions”).

Pigs:

Acute mastitis:

- Intramuscular use:

The recommended dosage is 2 mg / kg / day (1 ml / 50 kg) in a single daily injection.
Treatment duration is 3 days.

In order to reduce the risk of particulate contamination of the product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.
The septum can be punctured up to 27 times. The user should choose the most appropriate vial size according to the target species to treat.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Cattle:

- Respiratory infections (intramuscular route, 8 mg/kg single dose)
  Meat and offal: 3 days
  Milk: 72 hours
- Acute mastitis (intramuscular or subcutaneous route, 2 mg/kg single daily injection for 3 to 5 days)
  Meat and offal: 6 days
  Milk: 36 hours

Pigs (sows):

- Intramuscular use
  Meat and offal: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in the original package in order to protect from light.
Do not use after the expiry date stated on the outer carton and immediate label.
Shelf-life after first opening of the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

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

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.

Quinolones should only be used based upon susceptibility testing. The efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis induced by gram positive bacteria. 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 using this product.
- In case of contact with skin or eyes, rinse with plenty of water. Care should be taken to avoid accidental self injection.
- Accidental self-injection can induce a slight irritation.
- In case of accidental self injection, seek medical advice and show the label to the doctor.
- Wash hands after use.

Use during pregnancy
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effect.

Dose of 2 mg/kg body weight:
Can be used during pregnancy and lactation.
The safety of the veterinary medicinal product has been established in cow during gestation and suckling pigs and calves when used in cow and sow.

Dose of 8 mg/kg body weight:
The safety of the veterinary medicinal product has not been established in pregnant cow or in suckling calves when used in cow. Therefore, this dose regimen should be use only accordingly to the benefit/risk assessment by the responsible veterinarian.

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

Overdose
No severe side-effects are to be expected at doses up to 3 or 5 times the recommended dose in cattle and pigs respectively.
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.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

.....

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