PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enroxil Max 100 mg/ml solution for injection for cattle
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of solution for injection contains 100 mg of enrofloxacin with 20 mg of benzyl alcohol (E1519) and 30 mg of n-butyl alcohol.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

For cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For subcutaneous use or intravenous use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Subcutaneous use:
Meat and offal: 14 days.
Milk: 84 hours

Intravenous use:
Meat and offal: 4 days.
Milk: 72 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.
Do not freeze.

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

Marketing authorisation holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
Virbac, 1ere Avenue, 2065 M, LID, 06516 Carros, France (for Italy only)

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enroxil Max100 mg/ml solution for injection for cattle
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml of solution for injection contains 100 mg of enrofloxacin with 20 mg of benzyl alcohol (E1519) and 30 mg of n-butyl alcohol.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

For cattle.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For subcutaneous use or intravenous use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Subcutaneous use:
Meat and offal: 14 days.
Milk: 84 hours

Intravenous use:
Meat and offal: 4 days.
Milk: 72 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.
Do not freeze.

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 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

Marketing authorisation holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET

Enroxil Max 100 mg/ml solution for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
Virbac, 1ere Avenue, 2065 M, LID, 06516 Carros, France (for Italy only)

Manufacturer for the batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
Virbac S.A., 1ère avenue, 2065 m L.I.D., 06516 Carros Cedex, France (For Portugal and Italy only)

2. NAME OF THE VETERINARY MEDICAL PRODUCT

Enroxil Max 100 mg/ml solution for injection for cattle (
Enrofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml of clear, yellow solution for injection contains 100 mg of enrofloxacin with 20 mg of benzyl alcohol (E1519) and 30 mg of n-butyl alcohol.

4. INDICATIONS

Enroxil Max (Enroxil 100, Powerflox Max, Floxatril Max) is indicated for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni* and *Mycoplasma* spp. where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.
Enroxil Max (Enroxil 100, Powerflox Max, Floxatril Max) is indicated for the treatment of local signs (inflammation, milk quality and yield) associated with peracute/acute mastitis in lactating dairy cattle caused by *E. coli*, where herd history and previous sensitivity testing indicate enrofloxacin as the drug of choice.

5. CONTRAINDICATIONS

Do not use for prophylaxis.
Do not administer in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Transient local reactions may occur at injection site.

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, ROUTES AND METHOD OF ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
Respiratory infections in cattle: Enroxil Max (Enroxil 100, Powerflox Max, Floxatril Max) is administered subcutaneously. A single dose of 7.5 mg/kg bodyweight (7.5 ml per 100 kg bodyweight)

E. coli mastitis in cattle: Enroxil Max (Enroxil 100, Powerflox Max, Floxatril Max) is administered intravenous. 5.0 ml per 100 kg body weight (5 mg enrofloxacin per kg bodyweight) daily for 2 days.

9. ADVICE ON CORRECT ADMINISTRATION

No more than 15 ml should be administered at one subcutaneous injection site.

10. WITHDRAWAL PERIOD

Subcutaneous use:
Meat and offal: 14 days
Milk: 84 hours

Intravenous use:
Meat and offal: 4 days
Milk: 72 hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Keep the container in the outer carton in order to protect from light.
Do not freeze.

Do not use after the expiry date stated on the bottle.

Shelf-life after first opening the container: 28 days.
Discard unused material.

12. SPECIAL WARNINGS

Warnings and precautions for use in animals
Normal sterile precautions should be taken.
The safety of the product has not been established in calves when administered by the intravenous route and use of this route of administration in calves is therefore not recommended.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, 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.

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.

Can be used during pregnancy and lactation.

Clinical signs seen in gross overdosage include lethargy, lameness, ataxia, slight salivation and muscle tremors. In accidental overdose there is no antidote and treatment should be symptomatic.

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

User warnings
This product is an alkaline solution. Any spillage onto the skin should be washed off immediately with water.
In the event of accidental splash into the eye, rinse with copious amounts of clean water. If irritation occurs, seek medical advice.
Do not eat, drink or smoke whilst using the product.
Care should be taken to 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.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

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

15. OTHER INFORMATION

Amber glass type 2 multi-dose vials of 100 ml with bromobutyl rubber stopper.

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