PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton (100 ml) and label (10 x 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COMFORION® VET 100 mg/ml solution for injection for horse, cattle and swine
Kefoprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance
Ketoprofen 100 mg
Excipients
Arginine
Benzyl alcohol
Citric acid monohydrate (E330)
Water for injections

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
10 x 100 ml

5. TARGET SPECIES

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horse: intravenously

Cattle: intravenously or intramuscularly

Swine: intramuscularly

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 4 days
Milk: zero days

9. SPECIAL WARNING(S), IF NECESSARY

None

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 10 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

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

Any unused product or waste materials should be disposed of in accordance with national 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

Orion Corporation
P.O. Box 65
FIN - 02101 Espoo

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

label (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COMFORION® VET 100 mg/ml solution for injection for horse, cattle and swine
Kefoprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance
Ketoprofen 100 mg
Excipients
Arginine
Benzyl alcohol
Citric acid monohydrate (E330)
Water for injections

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horse: IV
Cattle: IV or IM
Swine: IM

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 4 days
Milk: zero days

9. SPECIAL WARNING(S), IF NECESSARY

None.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 10 days.
Once broached, use by: …

11. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.
Do not freeze.
Keep the vial 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 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

Orion Corporation
Espoo, Finland

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PACKAGE LEAFLET

COMFORION® VET 100 mg/ml solution for injection for horse, cattle and swine

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

Marketing authorisation holder and manufacturer:

Orion Corporation
P.O. Box 65
FIN-02101 Espoo

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

COMFORION® VET 100 mg/ml solution for injection for horse, cattle and swine
Ketoprofen

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

COMFORION® VET is a clear, colourless or yellowish solution.

Active substance:
Ketoprofen 100 mg/ml

Excipients:
Arginine
Benzyl alcohol 10 mg/ml
Citric acid monohydrate (E330)
Water for injections

4. INDICATIONS

Horse: Anti-inflammatory and analgesic treatment of musculosceletal disorders. Alleviation of visceral pain associated with colic.

Cattle: Anti-inflammatory and analgesic treatment of mammary gland disorders. Reduction of pyrexia associated with respiratory disease in conjunction with antimicrobial treatment.

Swine: Reduction of pyrexia in respiratory tract disorders. Supportive treatment of post partum dysgalactiae syndrome, PDS (MMA-syndrome) in conjunction with antibiotic therapy.

5. CONTRAINDICATIONS

Hypersensitivity to ketoprofen or any of the excipients in the product. Severe hepatic, renal or cardiac insufficiency, gastro-intestinal ulceration, heavy bleeding or evidence of blood dyscrasia.

6. ADVERSE REACTIONS

Repeated intramuscular injections may cause mild transient irritation. Due to the mechanism of action of ketoprofen (inhibition of the prostaglandin synthesis), gastric and intestinal irritation or ulceration or renal intolerance may occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse, cattle, swine

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Horse: 2.2 mg ketoprofen/kg bodyweight/day intravenously. For example, 11 ml/500 kg/day by intravenous injection for up to 3 days.

Cattle: 3 mg ketoprofen/kg bodyweight/day intravenously or intramuscularly. For example, 3 ml/100 kg/day by intravenous or deep intramuscular injection for up to 3 days.

Swine: 3 mg ketoprofen/kg bodyweight/day intramuscularly. For example, 3 ml/100 kg/day by deep intramuscular injection for up to 3 days.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Meat and offal: 4 days
Milk: zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 30 °C.
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

Do not use after the expiry date stated on the carton and label after EXP.
Shelf-life after first opening the container: 10 days.

12. SPECIAL WARNINGS

Avoid intra-arterial injections. Do not exceed the recommended dose or the duration of treatment. Use with precaution in dehydrated or hypotensive animals. In colic, a subsequent dose may be given only after a thorough re-examination. The use of ketoprofen is not recommended in foals under the age of 15 days. Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require a reduced dosage and careful management.

Avoid splashes to the skin and eyes. Wash hands after use. If accidental skin or eye contact occurs, irrigate thoroughly with water. In case of accidental self injection, seek medical advice.

The safety of ketoprofen has been investigated in pregnant laboratory animals (rats, mice, rabbits) and cattle. No adverse effects were noted. As the safety of ketoprofen has not been assessed in pregnant mares or sows, the product should be used in these cases only accordingly to the benefit/risk assessment by the responsible veterinarian.

Other non-steroidal anti-inflammatory drugs should not be used concomitantly or within 24 hours from administration of the product. Competition on plasma protein binding sites may lead to intoxication. Concurrent administration with diuretics, anticoagulant therapy and nephrotoxic drugs should be avoided.

In the absence of incompatibility 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

09.05.2012

15. OTHER INFORMATION

Package size:
1x100 ml (1 vial of 100 ml in a cardboard box)
10x100 ml (a shrink-wrapped package containing 10 cardboard boxes)

Not all pack sizes may be marketed.