PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Comforion vet 100 mg/ml solution for injection for horse, cattle and swine

2. Composition

Active substance:
Ketoprofen 100 mg/ml

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

Comforion vet is a clear, colourless to brownish-yellowish solution.

3. Target species

Horse, cattle and swine

4. Indications for use

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

Do not use in cases of hypersensitivity to the active substance or to any of the excipients. Do not use in animals suffering from severe hepatic, renal or cardiac insufficiency, gastro-intestinal ulceration, heavy bleeding or evidence of blood dyscrasia.

6. Special warnings

Special precautions for safe use in the target species:
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
Non-steroidal anti-inflammatory drugs (NSAIDs) such as ketoprofen may cause drug-induced photosensitivity reactions.
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 immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
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.

Interaction with other medicinal products and other forms of interaction:
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.

Major incompatibilities:
In the absence of incompatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Horse, cattle, swine:

Undetermined frequency (cannot be estimated from the available data):
Injection site reactions: injection site irritation Digestive tract disorders: gastric irritation, gastric ulcer, small intestine ulcer Renal and urinary disorders: renal intolerance

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

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 periods

Meat and offal: 4 days
Milk: zero days

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.
Keep the vial in the outer carton in order to protect from light.
After first opening the immediate packaging: Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number [To be completed nationally]

Pack sizes: 50 ml, 100 ml, 10 x 50 ml, 10 x 100 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

01/05/2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:
Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

VetViva Richter GmbH,
Durisolstrasse 14, 4600 Wels,
Austria

Local representatives and contact details to report suspected adverse reactions:
[To be completed nationally]