SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
1 ml contains ketoprofen 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Arginine	
Benzyl alcohol	10 mg/ml
Citric acid monohydrate (E330)	
Water for injections	

Clear, colourless to brownish-yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Horse, cattle, swine

3.2 Indications for use for each target species

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.

3.3 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 with evidence of blood dyscrasia.

3.4 Special warnings for each target species

None.

3.5 Special precautions for use

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. See section 3.7 regarding the use of the product in pregnant mares and sows.

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.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy or 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.

3.8 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.

3.9 Administration routes and dosage

Horse: 2.2 mg ketoprofen/kg bodyweight/day intravenously. For example, 11 ml/500 kg/day by intravenous injection for up to 3 days. In colic, see section 3.5, Special precautions for use.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The signs of overdose are listed in section 3.6. Treatment is symptomatic.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 4 days
Milk: zero days

4. PHARMACOLOGICAL PROPERTIES

4.1 ATCvet code: QM01AE03

4.2 Pharmacodynamics

Ketoprofen is a non-steroidal anti-inflammatory drug belonging to the 2-arylpropionic acid group of NSAIDs. In addition to the anti-inflammatory effect, it also has an anti-pyretic and analgesic effect. The pharmacological mechanism of action of ketoprofen is based on the inhibition of the cyclo-oxygenase and lipoxygenase. Ketoprofen also prevents the formation of bradykinin and stabilises the cell membranes of lysosomes, which inhibits the release of lysosomal enzymes that mediate tissue destruction.

4.3 Pharmacokinetics

Ketoprofen is rapidly absorbed after intramuscular administration. The measured maximum plasma concentration at 30 minutes from a single dose injection is 16.3 mg/l in swine and 9.7 mg/l in cattle. Ketoprofen binds approximately 95% to plasma proteins and its bioavailability after intramuscular administration is 80–100%. The plasma half life is approximately 1 hour in horses, approximately 2.5 hours in cattle, and 2–3 hours in swine. Only minor quantities of ketoprofen are transferred to milk. Ninety per cent of the dose is eliminated in the urine primarily as metabolites. Elimination from synovial fluid is delayed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Amber glass vials type II, with bromobutyl rubber stopper type I and aluminium caps.

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

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14/11/2022

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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