1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 100 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
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**
Benzyl alcohol	10 mg
L-Arginine	
Citric Acid Monohydrate	
Water for Injection	

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle.

3.2 Indications for use for each target species

In the horse, the veterinary medicinal product is indicated for:
- the alleviation of inflammation and pain associated with musculoskeletal disorders.
- the alleviation of visceral pain associated with colic.

In cattle, the veterinary medicinal product is indicated for:
- the supportive treatment of parturient paresis associated with calving;
- reducing the pyrexia and distress associated with bacterial respiratory disease when used in connection with anti microbial therapy as appropriate;
- reducing the clinical signs of mastitis associated with acute endotoxin mastitis;
- improving the recovery rate in acute clinical mastitis, caused by gram negative micro-organisms, in conjunction with antimicrobial therapy;
- reducing oedema of the udder associated with calving

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.
Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia or hypersensitivity to the product.

3.4 Special warnings

Use in any animals 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 use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid intra-arterial injection.
Do not exceed the stated dose or duration of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid splashes on the skin and eyes. Irrigate thoroughly with water should this occur.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, horses.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastric irritation Renal disorder

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 the national competent authority via the national reporting system. See the package leaflet for contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during pregnancy in mares, as the effects of ketoprofen on fertility, pregnancy or foetal health of horses have not been determined. Can be used during pregnancy and lactation in cattle.

3.8 Interaction with other medicinal products and other forms of interaction

Some NSAID's may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects. Concurrent administration with nephrotoxic drugs should be avoided.

3.9 Administration routes and dosage

Intramuscular or intravenous use.

Horses:
For use in musculo-skeletal conditions, the recommended dosage is 2.2 mg ketoprofen/kg, i.e. 1 ml of the veterinary medicinal product/45 kg bodyweight, administered by intravenous injection once daily for up to 3 to 5 days. For use in equine colic, the recommended dosage is 2.2 mg/kg (1 ml/45 kg) bodyweight, given by intravenous injection for immediate effect. A second injection may be given if colic recurs.

Cattle:
The recommended dose is 3 mg ketoprofen/kg bodyweight, i.e. 1 ml of the veterinary medicinal product/33 kg bodyweight, administered by intravenous or deep intramuscular injection once daily for up to 3 days. The stopper cannot be broached more than 45 times. When treating large groups of animals at one time, use an automatic dosing device.

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

No clinical signs were observed when the veterinary medicinal product was administered to horses at 5 times the recommended dose for 15 days, or to cattle at 5 times the recommended dose for 5 days.

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

Horses:
Meat and offal: 1 day.
Not authorised for use in mares producing milk for human consumption.

Cattle :
Meat and offal: - following intravenous administration – 1 day.
- following intramuscular administration – 4 days.
Milk: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AE03

4.2 Pharmacodynamics

Ketoprofen is a derivative of phenylpropionic acid, and belongs to the non-steroidal anti-inflammatory group of drugs. Like all such substances, its principal pharmacological actions are anti-inflammatory, analgesic and anti-pyretic. The mechanism of action is related to the ability of ketoprofen to interfere with the synthesis of prostaglandins from precursors such as arachidonic acid.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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 store above 25 ºC.
Protect from light.

5.4 Nature and composition of immediate packaging

50, 100 or 250 ml type II brown glass vials with chlorobutyl stopper.
50, 100 or 250 ml amber multilayer plastic (Polypropylene/Adhesive/ Ethylene vinyl alcohol layer/ Adhesive/ polypropylene) vials with bromobutyl stopper.
Cardboard box of 1 vial.

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

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/051/001

8. DATE OF FIRST AUTHORISATION

15/03/1996

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

24/04/2026

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).