SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 10% solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: Ketoprofen 100mg/ml

Preservative: Benzyl alcohol 10mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1. Target species

Horses, cattle, pigs.

4.2. Indications for use, specifying the target species

In the horse, Ketofen 10% is indicated for:

- the alleviation of inflammation and pain associated with musculoskeletal disorders;
- the alleviation of visceral pain associated with colic.

In cattle, Ketofen 10% 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 conjunction with antimicrobial therapy as appropriate;
- improving the recovery rate in acute clinical mastitis, including acute endotoxin mastitis, caused by gram negative micro-organisms, in conjunction with antimicrobial therapy;
- reducing oedema of the udder associated with calving;
- reducing pain associated with lameness.

In pigs, Ketofen 10% is indicated for:

- reducing the pyrexia and respiratory rate associated with bacterial or viral respiratory disease when used in conjunction with antimicrobial therapy as appropriate;

- the supportive treatment of Mastitis Metritis Agalactia Syndrome in sows, in conjunction with antimicrobial therapy as appropriate.

4.3. Contra-indications

Do not administer to horses, cattle or pigs that have previously shown a hypersensitivity to ketoprofen.

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.

4.4. Special warnings for each target species

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

4.5. Special precautions for use

i) Special precautions for use in animals
Avoid intra-arterial injection.
Do not exceed the stated dose or duration of treatment.

ii) Special precautions to be taken by the person administering the medicinal product to the animals

In case of accidental self-injection seek medical advice.
Wash hands after use.

Avoid splashes on the skin and eyes. Irrigate thoroughly with water should this occur. If irritation persists seek medical advice.

4.6. Adverse reactions (frequency and seriousness)

In common with all NSAIDs, due to their action of inhibition of prostaglandin synthesis, there can be the possibility in certain individuals of gastric or renal intolerance.

4.7. Use during pregnancy, lactation or lay

As the effects of ketoprofen on fertility, pregnancy or foetal health of horses have not been determined, KETOFEN 10% should not be administered to pregnant mares. KETOFEN 10% may be given to pregnant and lactating cattle. It is indicated for use in lactating sows.

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

Some NSAIDs 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.

4.9. Amounts to be administered and administration route

Horse:

For use in musculo-skeletal conditions, the recommended dosage is 2.2mg ketoprofen/kg i.e. 1ml of KETOFEN 10%/45kg bodyweight, administered by intravenous injection once daily for up to 3 to 5 days.

For use in equine colic, the recommended dosage is 2.2mg/kg (1ml/45kg) bodyweight, given by intravenous injection for immediate effect. A second injection may be given if colic recurs.

Cattle:
The recommended dose is 3mg ketoprofen/kg bodyweight, i.e. 1ml of KETOFEN 10%/33kg bodyweight, administered by intravenous or deep intramuscular injection once daily for up to 3 days.

Pigs:
The recommended dose is 3mg ketoprofen/kg bodyweight, i.e. 1ml of KETOFEN 10%/33kg bodyweight, administered once by deep intramuscular injection. The stopper cannot be broached more than 45 times. When treating large groups of animals at one time, use an automatic dosing device.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

No clinical signs were observed when KETOFEN 10% was administered to horses at 5 times the recommended dose for 15 days, to cattle at 5 times the recommended dose for 5 days, or to pigs at 3 times the recommended dose for 3 days.

Horses have been found to tolerate intravenous dosages of ketoprofen of 2.2, 6.6 and 11.0 mg/kg once daily for 15 consecutive days (i.e. up to 5 times the recommended dose for three times the recommended duration) with no evidence of toxic effects.

Ketoprofen is similarly well-tolerated in cattle, where doses of up to 15mg/kg/day (5 times recommended dose) for 5 consecutive days have been given without significant adverse effects. The product has been safely given to calves as young as 3 days of age, and to pregnant and lactating cattle. Ketoprofen is well tolerated in pigs. Doses of 9mg/kg/day (3 times the recommended dose) for 3 consecutive days have been given with no significant adverse effects.

4.11. Withdrawal periods

Horses, cattle and pigs must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after the following periods from the last treatment:

Horses	–	1 day
Cattle	–	following intravenous administration: 1 day
	–	following intramuscular administration: 4 days
Pigs	–	4 days

There is no withholding period necessary for the milk of treated cattle.

5. PHARMACOLOGICAL PROPERTIES

ATCVet Code: **QM01AE03**

5.1. Pharmacodynamic properties

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.

Following intravenous injection in the horse, the onset of musculo-skeletal anti-inflammatory activity occurs by 2 hours, and reaches a peak at about 12 hours. It is still measurable 24 hours after each dose.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

L Arginine
Benzyl
Alcohol
Citric Acid
Monohydrate Water
for Injections

6.2. Major incompatibilities

None known.

6.3. Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Do not store above 25°C.
Keep the multilayer plastic vial in the outer carton in order to protect from light.
Discard unused material safely.

6.5. 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
Not all pack sizes may be marketed

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER

Vm 14966/3015

9. DATE OF FIRST AUTHORISATION

12 February 1992

10. DATE OF REVISION OF THE TEXT

September 2025

11. ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable.

Gavin Hall
Approved: 30 September 2025