Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 10 % Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:
Ketoprofen 100 mg/ml

Preservative:
Benzyl alcohol 10 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, cattle

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 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.

4.3 Contraindications

Do not administer to horses or cattle 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 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.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

In common with all NSAID's, due to their action of inhibition of prostaglandin, 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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

Horse:
For use in musculo-skeletal conditions, the recommended dosage is 2.2 mg ketoprofen/kg, i.e. 1 ml of Ketofen 10%/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 Ketofen 10%/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.

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, or to cattle at 5 times the recommended dose for 5 days.

4.11 Withdrawal period(s)

Horses and cattle 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

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-Arginine
Benzyl Alcohol
Citric Acid Monohydrate
Water for Injection

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Following withdrawal of the first dose, use the product within 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Protect from light.

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

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

Unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/051/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 March 1996
Date of last renewal: 15 March 2006

10 DATE OF REVISION OF THE TEXT

May 2019