SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 1% solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Ketoprofen 10 mg/ml

Preservative
Benzyl alcohol 10 mg/ml

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

For the relief of pain and inflammation associated with musculoskeletal and other painful disorders in the dog and cat.

4.3 Contra-indications

Do not use in animals suffering from cardiac, hepatic, renal disease, where there is a possibility of gastrointestinal ulceration or bleeding or where there is evidence of blood dyscrasia.
Do not administer other non-steroidal anti-inflammatory drugs concurrently or within 24 hours of each other.
Do not use in animals known to be hypersensitive to the active substance.
Do not administer with diuretics or anticoagulants.

4.4 Special warnings for each target species

Use in any animal less than six 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. Refer also to paragraphs 4.3 and 4.5.

4.5 Special precautions for use

i. Special precautions for use in animals

Although local tolerance is not a problem, perivenous injection should be avoided.
Do not exceed the stated dose or duration of treatment.
Use in very young or old animals may involve additional risk. If such a use cannot be avoided, animals require careful clinical management.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
Concurrent use of potentially nephrotoxic drugs should be avoided.
Do not mix with other substances in the same syringe.

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 contact with the skin and splashes to the eyes. Irrigate with copious amounts of water as necessary.

4.6 Adverse reactions (frequency and seriousness)

Some signs of digestive intolerance (vomiting and diarrhoea) have been observed in certain rare cases. They rapidly disappear when treatment is stopped.

Slight transient swelling or local oedema is occasionally observed after subcutaneous or intramuscular injection.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer other NSAIDs concurrently or within 24 hours of each other.
Do not administer with diuretics or anticoagulants.
Gastrointestinal tract ulceration may be exacerbated by corticosteroids in patients given non-steroidal anti-inflammatory drugs.
Concurrent administration of potentially nephrotoxic drugs (e.g. aminoglycoside antibiotics) should be avoided.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

4.9 Amounts to be administered and administration route

The recommended dose is 2 mg ketoprofen per kg bodyweight i.e. 1 ml/5kg bodyweight, once daily for up to three consecutive days. Ketofen may be given by the subcutaneous, intramuscular or intravenous route in the dog, and by the subcutaneous route in the cat. If preferred, after one injection of Ketofen 1%, treatment may be followed on the next day with Ketofen tablets and continued on successive days for up to four days (i.e. up to five days in total).

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

The product is well tolerated by dogs and cats when administered at twice the recommended dose.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Antiinflammatory and antirheumatic products, non-steroids, propionic acid derivatives

ATCVet code: QM01AE03

5.1 Pharmacodynamic properties

Mode of action

Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) belonging to the propionic acid subclass of carbonylic acid derivative NSAIDs. Ketoprofen exerts three main pharmacological effects, which are common to all NSAIDs: anti-inflammatory, analgesic and antipyretic. The primary mechanism of action is inhibition of prostaglandin synthesis through interference with the cyclooxygenase pathway of arachidonic acid metabolism.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L Arginine
Benzyl Alcohol
Sodium Chloride
Citric Acid Monohydrate
Water for Injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

2 years.
In use shelf-life: 28 days.

6.4 Special precautions for storage

Protect from light. Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

Type I amber glass 20 ml bottles with chlorobutyl rubber bung and aluminium overseal, containing a clear, colourless solution.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials, 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 Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 15052/4145

9. DATE OF FIRST AUTHORISATION

18 May 1992

10. DATE OF REVISION OF THE TEXT

October 2022

Approved 11 October 2022