SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KETOFEN 20mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoprofen 20 mg per tablet

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet:
White uncoated tablets with a break line on one side. The score line is intended to facilitate ease of swallowing and not divide into equal doses.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use (specifying the target species)

For the relief of acute pain and inflammation associated with musculo-skeletal and other painful disorders in the dog and cat.

For the relief of pain in dogs associated with chronic osteoarthritic conditions.

4.3 Contraindications

Do not administer with diuretics or anti-coagulants.

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 a 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)

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

4.5 Special precautions for use

(i) Special precautions for use in animals
When treating acute pain or inflammation, do not exceed the stated dose of 1mg/kg or 5 day duration of treatment.
(ii) Special precautions for use to be taken by the person administering the medicinal product to the animals
Wash hands after use. In the event of accidental ingestion, seek medical advice and show the doctor what has been taken.

4.6 Adverse reactions (frequency and seriousness)

Vomiting and diarrhoea rarely but occasionally occur following treatment. These signs disappear rapidly when treatment is discontinued.

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

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 Amount(s) to be administered and administration route

For acute indications in dogs and cats, the recommended dosage is 1 mg of ketoprofen per kg body weight administered orally once daily for up to 5 days. Ketofen tablets may be given on the day following administration of Ketofen 1% injection to maintain treatment for up to a total of 5 days.
For chronic pain in dogs, the recommended dosage is 0.25 mg of ketoprofen per kg body weight administered once daily. The recommended duration of treatment is up to 30 days. If continued

treatment is indicated beyond the thirty days, the animal should first be re-examined by the veterinarian.

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

The product is well tolerated by dogs and cats at three times the recommended dose of 1 mg/kg, i.e., at 3 mg/kg.

Ketoprofen is well tolerated in dogs at five times the recommended dose of 0.25 mg/kg for up to 90 days, i.e., at 1.25 mg/kg.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

SUMMARY PRESENTATION OF THE ACTIVE SUBSTANCE
Ketoprofen is a nonsteroidal anti-inflammatory drug (NSAID) belonging to the propionic acid subclass of carbonylic acid derivatives. The primary mechanism of action is inhibition of prostaglandin synthesis through interference with the cyclo-oxygenase pathway of arachidonic acid metabolism.

ATC Vet Code: QM01AE03

5.1 Pharmacodynamic properties

Ketoprofen exerts three main pharmacological effects, which are common to all NSAIDs: anti-inflammatory, analgesic and antipyretic. Ketoprofen has been shown to have potent activity against acute, subacute and chronic inflammation in the classical models of inflammation.

5.2 Pharmacokinetic properties

For single administration of ketoprofen to dogs and cats by oral route, there is proportionality of dose. Ketoprofen elimination occurs more rapidly in the cat than the dog. As in the dog, the bioavailability parameters appear to be good with rapid resorption and bioavailability. Oral administration in cats is generally represented by a two-compartment model, with the dogs represented by a one-compartment model.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Maltodextrine Saccharose
Magnesium Stearate
Lactose Monohydrate

6.2 Major incompatibilities

None observed.

6.3 Shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time.

3 years.

6.4 Special precautions for storage

Do not store above 250C.

6.5 Nature and composition of immediate packaging

Cartons containing 5 aluminium foil blister packs of 10 tablets.
Cartons containing 10 aluminium foil blister packs of 10 tablets.
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 product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
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High Wycombe
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/4147

9. DATE OF FIRST AUTHORISATION

30 April 1992

10. DATE OF REVISION OF THE TEXT

October 2022

Approved 14 October 2022