PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 1% Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 10 mg Ketoprofen

Preservavtive: Benzyl alcohol 1% w/v

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs and Cats

6. INDICATION(S)

For the alleviation of inflammation and pain associated with musculo-skeletal disorders in dogs and cat

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer by s/c, i/m or i/v injection in the dog and by s/c injection in cats at 1 ml/5 kg body weight (equivalent to 2 mg ketoprofen per kg bodyweight) once daily for up to 3 consecutive days.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Avoid the introduction of contamination during use.

10. EXPIRY DATE

In use expiry date: 28 days

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

N/A

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

To be supplied only on veterinary prescription

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4145

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 1% Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains 10 mg Ketoprofen

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Preservative: benzyl alcohol 1% w/v

4. ROUTE(S) OF ADMINISTRATION

Administer by s/c, i/m or i/v injection in the dog and by s/c injection only in cats at 1 ml/5 kg bodyweight once daily for up to 3 consecutive days.

5. WITHDRAWAL PERIOD

N/A

6. BATCH NUMBER

7. EXPIRY DATE

In use shelf life: 28 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 1% Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A clear, sterile aqueous solution for injection containing 10 mg ketoprofen per ml. Benzyl alcohol is added at 1% w/v as a preservative.

4. INDICATION(S)

Ketoprofen is a potent, non steroidal anti-inflammatory and anti-ryretic analgesic. Ketofen 1% is indicated for the relief of pain and inflammation associated with musculo-skeletal and other painful disorders in the dog and cat.

5. CONTRAINDICATIONS

Do not exceed the stated dose or the duration of treatment. Use is contra-indicated 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. Do not administer other non-steroidal anti-inflammatory drugs (NSAIDS) concurrently or within 24 hours of each other. Do not administer with diuretics or anti-coagulants. Some NSAIDS may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects. Use in very young or old animals may involve additional risk. If such use cannot be avoided animals may require careful clinical management. Avoid use in any dehydrated, hypovolaemic or hypotensive animal as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs (eg

aminoglycoside antibiotics) should be avoided. Do not mix with other substances in the same syringe. Do not administer to pregnant animals. Although local tolerance is not a problem, perivenous injection should be avoided. Vomiting and diarrhoea rarely, but occasionally occur following treatment. These effects rapidly disappear when the treatment is discontinued. Slight transient swelling or local oedema is occasionally observed after sub cutaneous or intramuscular injection. Gastro-intestinal tract ulceration may be exacerbated by corticosteroids in patients given non-steroidal anti-inflammatory drugs.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Dog and Cat

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

When the container is broached for the first time, the date on which any product remaining in the container must be discarded should be calculated. A statement of the in-use shelf life of the product is given in this package leaflet. The discard date should be written in the space provided on the carton.

12. SPECIAL WARNING(S)

For Animal Treatment Only

Keep out of reach of children.

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. Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

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Approved 11 October 2022