

**PARTICULARS TO APPEAR ON THE OUTER PACKAGES 50, 100, 250 ML**  
**And immediate packaging for the 100 and 230 ML**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Ketofen 10% Solution for Injection

Ketoprofen

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains 100 mg ketoprofen

Preservative: benzyl alcohol 10 mg/ml

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

50ml, 100ml, 250ml

**5. TARGET SPECIES**

Horses, cattle and pigs

**6. INDICATION(S)**

In horses, 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 microorganisms, 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 distress associated with bacterial or viral respiratory disease when used in conjunction with anti-microbial therapy as appropriate.
- the supportive treatment of Mastitis Metritis Agalactia Syndrome in sows, in conjunction with anti-microbial therapy as appropriate.

## **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Horses: 1 ml/45 kg bodyweight (2.2 mg/kg) by IV injection.  
Cattle: 1 ml/33 kg bodyweight (3 mg/kg) by IV or IM injection.  
Pigs: 1 ml/33 kg bodyweight (3 mg/kg) by IM injection.

## **8. WITHDRAWAL PERIOD**

Horses: 1 day  
Cattle: meat: - IV administration: 1 day  
                  - IM administration: 4 days  
                  milk: zero days  
Pigs: 4 days

## **9. SPECIAL WARNING(S), IF NECESSARY**

For all contra-indications and safety warnings, See package leaflet.

## **10. EXPIRY DATE**

EXP {month /year}  
Shelf-life after first opening the container: 28 days  
Once opened, use by \_\_\_\_\_

## **11. SPECIAL STORAGE CONDITIONS**

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

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

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

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

POM-V

For animal treatment only.

To be supplied only on veterinary prescription.

## **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of sight and 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 15052/4146

**17. MANUFACTURER'S BATCH NUMBER**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**50 ML**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Ketofen 10% Solution for Injection

Ketoprofen

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Each ml contains 100mg ketoprofen

Preservative: benzyl alcohol 10 mg/ml

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

50ml

**4. ROUTE(S) OF ADMINISTRATION**

Horses: 1 ml/45 kg bodyweight (2.2mg/kg) by IV injection.

Cattle: 1 ml/33 kg bodyweight (3 mg/kg) by IV or IM injection.

Pigs: 1 ml/33 kg bodyweight (3 mg/kg) by IM injection.

**5. WITHDRAWAL PERIOD**

Horses: 1 day

Cattle: meat: - IV administration: 1 day

- IM administration: 4 days

milk: zero

Pigs: 4 days.

**6. BATCH NUMBER**

**7. EXPIRY DATE**

## **8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

Read package leaflet before use. To be supplied only on veterinary prescription. For animal treatment only.

## PACKAGE LEAFLET:

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

Marketing Authorisation Holder:

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

Manufacturer responsible for batch release

Ceva Santé Animale  
10 Av de la Ballastière  
33500 Libourne  
France

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 10% Solution for Injection

Ketoprofen

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

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

### 4. INDICATION(S)

Ketoprofen is a non-steroidal anti-inflammatory agent with analgesic and antipyretic properties.

In horses, 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 microorganisms, 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 distress associated with bacterial or viral respiratory disease when used in conjunction with anti-microbial therapy as appropriate.
- the supportive treatment of Mastitis Metritis Agalactia Syndrome in sows, in conjunction with anti-microbial therapy as appropriate.

## **5. CONTRAINDICATIONS**

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.

## **6. ADVERSE REACTIONS**

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.

## **7. TARGET SPECIES**

Horses, cattle and pigs.

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

Horse: For use in musculoskeletal 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 breached more than 45 times. When treating large groups of animals at one time, use an automatic dosing device.

## **9. ADVICE ON CORRECT ADMINISTRATION**

### **10. WITHDRAWAL PERIOD(S)**

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.

### **11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C.

Keep the multilayer plastic vial in the outer carton in order to protect from light.

Shelf life after first opening the container: 28 days

After withdrawal of the first dose use the product within 28 days. When the container is breached for the first time, the date on which any product remaining in the container should be discarded

should be calculated. A statement of the in-use shelf life of the product is given on the package leaflet. This

discard date should be written on the space provided on the label

Discard unused material.

Avoid the introduction of contamination during use.

Should any apparent growth or discoloration occur, the product should be discarded.

## **12. SPECIAL WARNING(S)**

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.

### **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 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.

### **Use during pregnancy and lactation:**

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.

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. This product has been safely given to calves as young as 3 days of age and to pregnant and lactating cattle.

### **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.

## **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

POM-V

For animal treatment only.

To be supplied only on veterinary prescription.

Vm 15052/4146

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

Approved 11 October 2022

