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 broached 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 broached 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