PACKAGE LEAFLET FOR:
NEFOTEK 100 mg/ml solution for injection for cattle, horses and pigs [AT, CZ, IE, PL, SK, UK, DE, FR, ES, HU, IT, SI]
COXOFEN 100 mg/ml solution for injection for cattle, horses and pigs [BE, DK, NL]

Ketoprofen

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

Marketing authorisation holder:
Vetpharma Animal Health, S.L
Les Corts, 23
08028 Barcelona
Spain

Manufacturer responsible for the batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona) Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEFOTEK 100 mg/ml solution for injection for cattle, horses and pigs [AT, CZ, IE, PL, SK, UK, DE, FR, ES, HU, IT, SI]
Ketoprofen

COXOFEN 100 mg/ml solution for injection for cattle, horses and pigs [BE, DK, NL]
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3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains: Ketoprofen, 100 mg; Benzyl alcohol (E1519), 10 mg.
A clear, colourless to yellow solution. Free from visible particles.

4. INDICATION(S)

Cattle: Anti-inflammatory and analgesic treatment of diseases in the musculoskeletal system and the udder.
Pigs: Anti-inflammatory and antipyretic treatment of Postpartum Dysgalactia Syndrome -PDS – ((Metritis Mastitis Agalactia Syndrome) and respiratory diseases.
Horses: Anti-inflammatory and analgesic treatment of diseases in the musculoskeletal system and joints.
Symptomatic analgesic treatment for colic. Postoperative pain and swelling.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, or to any of the excipients.
Do not use in animals suffering from gastro-intestinal lesions, haemorrhagic diathesis, blood dyscrasia, impaired hepatic, cardiac or renal function.
Do not use in foals in their first month of life.

Do not use other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

6. ADVERSE REACTIONS

In very rare cases (less than 1 animal in 10,000 animals, including isolated reports) these signs can be observed:

• temporary irritation after repeated intramuscular injections
• gastric and intestinal irritation or ulceration (due to ketoprofen mechanism of action including inhibition of prostaglandin synthesis)
• reversible inappetence after repeated administration to swine
• allergic reactions
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs and horses.

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

Cattle: Intramuscular use or Intravenous use
3 mg ketoprofen/kg b.w./day (equivalent to 3 ml of the product /100 kg b.w./day) for up to 3 days.
Pigs: Intramuscular use
3 mg ketoprofen/kg b.w./day (equivalent to 3 ml of the product/100 kg b.w./day) administered once.
Horses: Intravenous use
2.2 mg ketoprofen/kg b.w./day (equivalent to 1 ml of the product/45 kg b.w./day) for 3 to 5 days. In the case of colic, treatment should not be repeated until a clinical re-examination has been carried out.

9. ADVICE ON CORRECT ADMINISTRATION

Not more than 5 ml should be administered at one intramuscular injection site.
The stoppers must not be punctured more than 166 times.

10. WITHDRAWAL PERIOD

Cattle, horses, pigs:
Meat and offal: 4 days
Milk (bovine): Zero hours
Not authorised for use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the container in the outer carton. Protect from light.
Do not refrigerate or freeze
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container

should be discarded should be worked out. This discard date should be written in the space provided.

Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Use in animals 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 intra-arterial injection. Do not exceed the stated dose or duration of treatment.
Use with caution in dehydrated, hypovolemic or hypotensive animals as there is a potential risk of increased renal toxicity. In the case of colic a supplementary dose may only be given after a thorough clinical examination.
Sufficient drinking water must be supplied at all times during treatment

User Warnings
Take care to avoid accidental self injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to ketoprofen or benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid splashes on the skin and eyes. Rinse thoroughly with water should this occur. If irritation persists seek medical advice.
Wash hands after use.

Use during pregnancy, lactation or lay
The safety of ketoprofen has been investigated in pregnant laboratory animals, (rats, mice and rabbits) and in cattle, and showed no teratogenic or embryotoxic effects.
The product may be given to pregnant and to lactating cattle, and to lactating sows.
As the effect of ketoprofen on the fertility, pregnancy or foetal health of horses have not been determined, the product should not be administered to pregnant horses.. As the safety of ketoprofen has not been assessed in pregnant sows, the product should be used in these case according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
The veterinary medicinal product must not be administered in conjunction with, or within 24 hours of administration of other NSAIDs and glucocorticoids. Concurrent administration of diuretics, nephrotoxic drugs and anticoagulative drugs should be avoided.
Ketoprofen is highly bound to plasma proteins, and may displace or be displaced by other highly protein bound medicines, such as anticoagulants. Due to the fact that ketoprofen may inhibit platelet aggregation and cause gastrointestinal ulceration, it should not be used with other medicines that have the same profile of adverse drug reactions.

Overdose (symptoms, emergency procedures, antidotes)
No clinical signs were observed when the product was administered to horses at 5 times (11 mg/kg) the recommended dose for 15 days, to cattle at 5 times (15mg/kg/day) the recommended dose for 5 days, or to pigs at 3 times (9mg/kg/day) the recommended dose for 3 days
Ketoprofen can lead to hypersensitivity reactions and moreover might have a detrimental effect on the gastric mucosa. This may require cessation of ketoprofen treatment and introduction of symptomatic therapy.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Ketoprofen is a substance belonging to the group non-steroidal anti-inflammatory drugs (NSAIDs). Ketoprofen has anti-inflammatory, analgesic and antipyretic properties. Not all aspects of its mechanism of action are known. Effects are obtained partially by the inhibition of prostaglandin and leukotriene synthesis by ketoprofen, acting on cyclooxygenase and lipoxygenase respectively. The formation of bradykinin is also inhibited. Ketoprofen inhibits thrombocyte aggregation.

Pack Sizes: 100 ml and 250 ml.
Outer Packs: 1 unit of 100 ml and 250 ml.

Not all pack sizes may be marketed.