Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NEFOTEK 100 mg/ml solution for injection for cattle, horses and pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:	
Ketoprofen	100 mg
Excipients:	
Benzyl alcohol (E1519)	10 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection
A clear, colourless to yellow solution. Free from visible particles.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs and horses

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 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.

4.8 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.

4.9 Amounts to be administered and administration route

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.

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

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

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 (15 mg/kg/day) the recommended dose for 5 days, or to pigs at 3 times (9 mg/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.

4.11 Withdrawal Period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids
ATCvet code: QM01AE03

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.

5.2 Pharmacokinetic properties

After intravenous injection to horses the half-life is approx. 1 hour. The distribution volume is approx. 0.17 l/kg and the clearance approx. 0.3 l/kg. After intramuscular injection to cattle and pigs ketoprofen is quickly absorbed and the maximum plasma concentration of approx. 11 micrograms/ml is obtained within ½ to 1 hour. The mean absorption time is approx. 1 hour. The plasma half-life is 2 – 2 ½ hours. The bioavailability after intramuscular injection is 90 – 100% in cattle and pigs. In the case of repeated injections at 24 hour intervals ketoprofen exhibits linear and stationary kinetics since the above parameters remain unchanged. Ketoprofen is approx. 95% bound to plasma proteins.
Ketoprofen is metabolised mainly by the reduction of the ketone group to a main metabolite. Ketoprofen is quickly excreted; approx. 80% is eliminated within 12 hours after administration. 90% of the elimination takes place via the kidneys, mainly in metabolised form.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L Arginine
Benzyl alcohol (E1519)
Citric acid monohydrate (for pH adjustment)
Water for injection

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Keep the container in the outer carton. Protect from light.
Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

The product is packaged in amber type II glass vials of 100 ml and 250 ml.
The vials are closed with a type I rubber bromobutyl stopper oversealed with an aluminium cap. Vials are packaged in cardboard boxes containing 1unit.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Vetpharma Animal Health, S.L
Les Corts, 23
08028 Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10516/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th February 2012
Date of last renewal: 9th December 2016

10 DATE OF REVISION OF THE TEXT

December 2016