

## **Leaflet**

For Veterinary Use Only

### **VILPROFEN**

Solution For Injection

Veterinary Non-steroidal Antiinflammatory - Antirheumatismal

## **COMPOSITION**

It is a colorless or light yellow colored clear solution, containing 100 mg Ketoprofen per ml.

## **PHARMACOLOGICAL PROPERTIES**

### **Pharmacodynamic Properties**

Ketoprofen is a non-steroidal anti-inflammatory drug. In addition to its anti-inflammatory effect, it also has antipyretic and analgesic effects. The exact mechanisms of action are not fully understood. The pharmacological mechanism of action of ketoprofen is based on its effect on cyclooxygenase and lipoxygenase, which partially inhibits the synthesis of prostaglandins and leukotrienes. Ketoprofen also inhibits bradykinin formation and platelet aggregation, stabilizes lysosomal membranes, thereby preventing the release of lysosomal enzymes that contribute to tissue damage.

### **Pharmacokinetics Properties**

After intravenous injection in horses, the half-life is approximately 1 hour, the distribution volume is approximately 0.17 l/kg, and the clearance is approximately 0.3 l/kg. After intramuscular injection in cattle and pigs, ketoprofen is rapidly absorbed, and the maximum plasma concentration is approximately 11 micrograms/ml, achieved between ½ and 1 hour. The average absorption time is approximately 1 hour, and the plasma half-life is 2–2.5 hours. Following intramuscular injection, bioavailability in cattle and pigs is 90–100%. When administered at 24-hour intervals, ketoprofen exhibits linear and constant kinetics, as the above parameters remain unchanged. Approximately 95% of ketoprofen binds to plasma proteins.

Ketoprofen is primarily metabolized by reduction of the ketone group to a major metabolite. Ketoprofen is rapidly eliminated; approximately 80% is eliminated within 12 hours of administration. Approximately 90% of elimination occurs via the kidneys, primarily in the form of metabolites.

## **AREA OF USE/INDICATIONS**

### **Cattle:**

- Supportive treatment of birth-related birth paralysis,
- Relief of pain and fever in bacterial respiratory tract infections, in conjunction with appropriate etiological treatment,
- Support of recovery in acute clinical mastitis, including acute endotoxic mastitis caused by Gram-negative bacteria, in conjunction with appropriate etiological treatment,
- Alleviation of postpartum breast edema,
- Osteoarticular and musculoskeletal system pain,
- Facilitation of postpartum ambulation

### **Horse**

Diseases affecting the osteoarticular and musculoskeletal systems associated with acute pain and inflammation:

- Traumatic lameness
- Arthritis
- Osteitis, knee swelling

- Tendinitis, bursitis
- Naviculitis
- Laminitis
- Myositis

It is also used for the symptomatic treatment of post-operative inflammation, colic, and fever.

## **USAGE AND DOSAGE**

### **Cattle:**

It is administered 3 mg/kg bodyweight (3 ml for 100 kg body weight) intramuscularly or intravenously up to 3 days.

### **Horse:**

It is administered 2,2 mg/kg body weight (1 ml for 45 kg body weight) intravenously for 3-5 days. It should not be repeated unless clinically necessary and appropriate in cases of colic.

No more than 5 ml should be administered to one area in intramuscular administration.

It should be administered 10-30 minutes before the procedure to reduce post-operative pain.

An appropriate syringe should be used and body weight should be calculated accurately to avoid overdose.

## **SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES**

Use of the product in animals younger than 6 weeks and in elderly animals carries a higher risk. If use in these groups of animals is necessary, the dose should be reduced and the animals should be kept under observation. Avoid intra-arterial administration.

Do not exceed the specified dose and duration.

Use with caution in dehydrated, hypovolemic, and hypotensive animals due to the potential for increased renal toxicity.

Additional administration in cases of colic should only be performed after clinical examination. Ensure that animals have adequate access to drinking water during treatment.

**Use during pregnancy and lactation:** Safety studies in pregnant experimental animals (rats, mice, rabbits) and pregnant cows have not shown any teratogenic or embryotoxic effects of ketoprofen.

The product may be administered to pregnant and lactating cows.

Since the effects of ketoprofen on fertility, pregnancy, and the fetus in horses have not been studied, its use in pregnant mares is not recommended.

Intravenous administration should be performed slowly due to the risk of anaphylactic shock.

## **ADVERSE EFFECTS**

The following symptoms may occur very rarely:

- Temporary irritation in repeated intramuscular applications,
- Gastric and intestinal irritation or ulceration, renal intolerance (due to ketoprofen's inhibition of prostaglandin synthesis),
- Temporary loss of appetite in pigs after repeated application,
- Allergic reactions.

The following conversion is used to report the frequency of side effects:

- *Very common (more than 1 in 10 animals)*
- *Common (more than 1 in 100 animals but less than 10)*
- *Uncommon (more than 1 in 1,000 animals but less than 10)*

- *Rare (more than 1 in 10,000 animals but less than 10)*
- *Very rare (less than 1 in 10,000 animals)*

## **DRUG INTERACTIONS**

This product should not be used concurrently or within 24 hours of each other with glucocorticoids and other NSAID products.

It should not be used concurrently with diuretics, nephrotoxic drugs, and anticoagulants.

Ketoprofen binds to plasma proteins to a high degree; therefore, its binding may be affected by other drugs that bind to plasma proteins to a high degree, such as anticoagulants, or ketoprofen may affect the binding of these drugs to proteins.

Ketoprofen may inhibit platelet aggregation and cause gastrointestinal ulceration. Therefore, it should not be used concomitantly with other drugs that have this effect.

## **SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE**

No clinical side effects have been observed when administered at 5 times the recommended dose for 15 days in horses and 5 times the recommended dose for 5 days in cattle.

Ketoprofen may cause hypersensitivity reactions and serious damage to the gastric mucosa. In such cases, treatment should be discontinued and symptomatic treatment administered.

Excessive doses of NSAIDs may cause gastrointestinal ulceration, protein loss, and hepatic and renal damage. In tolerance studies conducted in pigs, erosive and/or ulcerative lesions were observed in the glandular and aglandular regions of the stomach when three times the therapeutic dose (9 mg/kg) was administered for three days and when the therapeutic dose (3 mg/kg) was administered for nine days.

Early signs of toxicity include loss of appetite, soft stools, and diarrhea.

## **WITHDRAWAL PERIODS**

**Meat: 4 days for cattle.**

**Milk: 0 days.**

## **CONTRAINDICATIONS**

Not to be used in animals known to be hypersensitive to any of the ingredients.

It should not be used in animals with significant liver, heart, or kidney dysfunction.

It should not be used in animals with gastrointestinal lesions, hemorrhagic diathesis, or blood dyscrasias.

It should not be used in foals younger than one month of age.

It should not be administered concurrently with other NSAIDs or within 24 hours before or after the administration of drugs in this class.

## **GENERAL WARNINGS**

Consult a veterinarian before use and if any unexpected effects occur. Keep out of reach of children and away from foodstuffs.

**PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON**

In case of accidental self-injection, seek immediate medical attention and show the product label/package insert to your doctor. Individuals who are sensitive to ketoprofen or other excipients should not come into contact with the product. Avoid contact with eyes and skin. In case of contact, wash the area thoroughly with water. If sensitivity persists in the affected area, consult a doctor. Wash your hands after use.

**STORAGE CONDITIONS AND SHELF LIFE**

Before and after opening, the product should be stored below 25°C, in the original packages, without being frozen or placed in the refrigerator. Protect from sunlight. Shelf life is 2 years. It should be consumed within 28 days after opening.

**DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES**

Used or remaining product should be disposed of according to the relevant regulations.

**COMMERCIAL PRESENTATION FORM**

50 ml and 100 ml amber-colored glass vials with cardboard boxes.

**PLACE AND CONDITIONS OF SALE**

It is sold in pharmacies and veterinary clinics with a veterinarian's prescription. (VHP)

**APPROVAL DATE OF LEAFLET: 14.02.2025****MARKETING AUTHORIZATION DATE AND NO: 20.06.2011 – 024/0054****MARKETING AUTHORIZATION HOLDER**

VİLSAN Veteriner İlaçları Tic. ve San. A.Ş.

Balıkhisar Mah. Balıkhisar Köy İçi Küme Evleri No:765A Akyurt/Ankara-Türkiye

**MANUFACTURER COMPANY**

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Balıkhisar Mah. Balıkhisar Köy İçi Küme Evleri No:765A Akyurt/Ankara-Türkiye

**Made in Türkiye**

**Box**

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It contains 100 mg Ketoprofen per ml.

**AREA OF USE/INDICATIONS**

It is used for the symptomatic treatment of acute pain and diseases affecting the osteoarticular and musculoskeletal systems regarding inflammation, and postoperative inflammation, colic, and fever in cattle and horses.

**USAGE AND DOSAGE**

**Cattle:** It is administered 3 ml for 100 kg body weight intramuscularly or intravenously up to 3 days.

**Horse:** It is administered 1 ml for 45 kg body weight intravenously for 3-5 days.

**Read the leaflet for detailed information.**

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