Only for Veterinary Use

Tolfenak®

Solution for Injection

Veterinary Anti-inflammatory

COMPOSITION

TOLFENAK Solution for Injection is a clear, colorless or light yellow sterile solution which contains 40 mg tolfenamic acid per ml.

PHARMACOLOGICAL PROPERTIES

Tolfenak Solution for Injection contains the non-steroid anti-inflammatory (NSAI) active substance, namely tolfenamic acid. Mechanism of action of tolfenamic acid (N-(2-methyl-3-chlorophenyl anthranilic acid) is based on inhibition of prostaglandins and synthesis of thromboxane by inhibiting the enzyme cyclo-oxygenase. It exerts anti-inflammatory, analgesic and anti-piretic effects.

Tolfenamic acid is rapidly absorbed from injection site. Distribution volume of tolfenamic acid is 1.3 L/kg for cattle. It is bound to plasma albumins by 97 percent. Based on high plasma concentration, it is distributed to liver, lungs, kidneys and other organs in gastrointestinal tract. However, cerebral concentration is low. Tolfenamic acid and metabolites may not overcome placental barrier. Tolfenamic acid is distributed at concentrations similar to plasma concentration in healthy and inflamed peripheral tissues and extra-cellular fluids. It is diffusely involved in enterohepatic circulation and accordingly, it remains in plasma for longer time. Elimination half-time is 8 - 15 hours for cattle.

It was reported that 4µg/ml (SC) reached through subcutaneous application, 3µg/ml (IM) reached through intramuscular application within 2 hours after 4 mg/kg tolfenamic acid had been administered via intramuscular or subcutaneous route in dogs.

Tolfenamic acid is excreted in non-metabolized active form in urine and faeces.

AREA OF USE/INDICATIONS

TOLFENAK Solution for Injection is used for anti-inflammatory, analgesic and anti-piretic treatment in cattle, dog and cat.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

It is recommended that TOLFENAK Solution for Injection is intravenously administered at dose of 4 mg/kg live body weight for mastitis in milch cow, while it is subcutaneously or intravenously administered twice in 48-hour intervals at dose of 2 mg/kg live body weight for respiratory system infections.

Practical dose:

Mastitis of cattle: 1 ml / 10 kg live body weight/day dose is administered once via intravenous route.

Respiratory system diseases of cattle: 1 ml / 20 kg live body weight dose is administered via subcutaneous or intravenous routes. If required, administration can be repeated 48 hours later.

In Dogs: 4 mg/kg / live body weight is administered via intramuscular and subcutaneous routes. It is recommended that it is concomitantly used with premedication agent in preoperative period for relieving postoperative pain. If required, administration can be repeated 24 hours later.

In Cats: 4 mg/kg / live body weight is administered only via subcutaneous route.

ADVERSE / SIDE EFFECTS

There is no finding which indicates intolerance to drug in cattle. It may lead to pain at injection site. Vomiting and diarrhea may rarely occur in dogs and cats following administration.

DRUG INTERACTIONS

Side effects may occur if it is administered in conjunction with other systemic non-steroidal anti-inflammatory drugs. It should not be used in conjunction with nephrotoxic drugs.

SYMPTOMS, PRECAUTIONS AND ANTIDOTE IN OVERDOSE

Recommended doses should not be exceeded during the treatment. Overdose may lead to nervous symptoms which can be symptomatically treated.

WARNINGS FOR THE DRUG RESIDUES IN NUTRIENTS

Withholding Period (WHP): Cattle should not be transferred to slaughtering throughout the treatment or within 3 days and 7 days following last intravenous and subcutaneous dose of the drug, respectively. Milk of cow obtained throughout treatment and within 1 day(2 milking) following last administration should not be offered to consumption by human.

CONTRAINDICATIONS

- It is contraindicated in animals with gastrointestinal disorder, renal, cardiac and hepatic insufficiency and hemorrhage.
- It should not be used in animals with known sensitivity against tolfenamic acid.
- It should not be used in conjunction with general anesthetics.
- Intramuscular administration is contraindicated for cattle. There is risk related with administration to 6-weeks old or younger animals and dose should be reduced in evitable conditions and animal should be kept under clinical monitoring.

During pregnancy: Use of NSAID is not recommended during pregnancy since they may influence labor mechanism.

GENERAL WARNINGS

Please refer to the veterinary surgeon before use and in case of an unexpected effect. **Keep out of the reach of children.**

STORAGE CONDITIONS AND SHELF LIFE

Keep at room temperature below 25℃ away from exposu re to sun light. After original package is opened, shelf life is 28 days should the preparation is stored at temperature below 25 C. Shelf life is 2 years from the date of production.

COMMERCIAL SUPPLY INDICATING COMPOSITION AND QUANTITY OF PACKAGING

It is commercially available in 20, 50 and 100 ml amber glass vials packed into cardboard boxes as well as 250 ml amber glass vials packed into plastic box.

SALE PLACE AND CONDITIONS

It is sold in the veterinary offices and the pharmacies with prescription written by veterinary surgeon (VP).

PROSPECTUS APPROVAL DATE

DATE AND NUMBER OF LICENSE AWARDED BY THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS:

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk.

No: 18, 34896 Pendik-ISTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat