

CLOFENAC

Injection

For Veterinary Use Only

COMPOSITION:

Each ml contains:

Aceclofenac as Sodium (MS) eq.to Aceclofenac 25mg

INDICATIONS:

CLOFENAC Injection is indicated for the treatment of pyrexia, traumatic fever, post-operative therapy, rheumatic fever, FMD, metritis and other ailments associated with pain and inflammation in domestic animals.

PHARMACOLOGY:

MODE OF ACTION:

Through COX-2 inhibition, Aceclofenac downregulates the production of various inflammatory mediators including prostaglandin E₂ (PGE₂), IL-1 β , and TNF from the arachidonic acid (AA) pathway. Inhibition of IL-6 is thought to be mediated by diclofenac converted from Aceclofenac. Suppressed action of inflammatory cytokines decreases the production of reactive oxygen species.

PHARMACODYNAMICS:

Aceclofenac is a NSAID that inhibits both isoforms of COX enzyme, a key enzyme involved in the inflammatory cascade. COX-1 enzyme is a constitutive enzyme involved in prostacyclin production and protective functions of gastric mucosa whereas COX-2 is an inducible enzyme involved in the production of inflammatory mediators in response to inflammatory stimuli. Aceclofenac displays more selectivity towards COX-2 (IC₅₀ of 0.77 μ M) than COX-1 (IC₅₀ of > 100 μ M), which promotes its gastric tolerance compared to other NSAIDs.

PHARMACOKINETICS:

Aceclofenac is rapidly and completely absorbed from the gastrointestinal tract and circulates mainly as unchanged drug following oral administration. Peak plasma concentrations are reached around 1.25 to 3 hours post-ingestion, and the drug penetrates into the synovial fluid where the concentration may reach up to 60% of that in the plasma. There is no accumulation in regular dosing, with similar maximum plasma concentration (C_{max}) and time to reach peak plasma concentration (T_{max}) after single and multiple doses.

The volume of distribution is approximately 25 L. It is reported to be highly protein-bound (>99%). 4'-hydroxyaceclofenac is the main metabolite detected in plasma however other minor metabolites include diclofenac, 5-hydroxyaceclofenac, 5-hydroxydiclofenac, and 4'-hydroxydiclofenac. It is probable that the metabolism of aceclofenac is mediated by CYP2C9.

The main route of elimination is via the urine where the elimination accounts for 70-80% of clearance of the drug. Approximately two thirds of the administered dose is excreted via the urine, mainly as glucuronidated and hydroxylated forms of aceclofenac. About 20% of the dose is excreted into feces.

DOSAGE AND ADMINISTRATION:

Administer the following dose by deep intramuscular injection.

Horses & Camels: 25-30 per Kg bodyweight.

Cattle & Buffalo: 20-25ml per 300Kg body weight.

Goat & sheep: 3-5ml per 50 Kg bodyweight.

Dogs & Cats: 0.5-1ml per 5 Kg bodyweight.

Adverse Effects: Some common adverse effects include

- Gastro-intestinal disorders (dyspepsia, abdominal pain, nausea
- Rash
- Urticarial
- Symptoms of enuresis
- Headache
- Dizziness
- Drowsiness

CONTRAINDICATIONS:

Aceclofenac injection is contraindicated in patients who have previously shown hypersensitivity reactions.

DRUG INTERACTIONS: No data regarding the interactions of Aceclofenac was found.

WITHDRAWAL TIME:

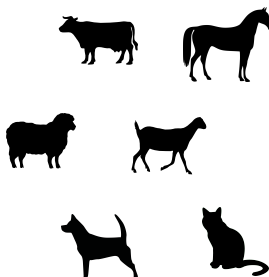
Meat: 28 days

Milk: 07 days

PRECAUTIONS:

- It should not be combined with other drugs in the same syringe.
- Consult the veterinarian before use.
- Store between 15-25°C at cool and dry place.
- Keep out of the reach of children.

Innovator's Specs



Manufactured by:
Selmores Pharmaceuticals (Pvt) Ltd.
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ISO CERTIFIED COMPANY