

Leaflet

For Veterinary Use Only
FLUVIL
Solution For Injection
Veterinary Non-Steroid Antiinflammatory

COMPOSITION

It is a colorless or pale yellow clear solution, containing Flunixin meglumine equivalent to 50 mg Flunixin per ml.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Flunixin meglumine is a non-selective reversible inhibitor of the cyclooxygenase (COX) enzyme, which leads to the conversion of arachidonic acid into cyclic endoperoxides, which are then converted into prostaglandins, prostacyclins, and thromboxanes.

Flunixin acts as a non-selective reversible inhibitor of the COX enzyme, which converts arachidonic acid into unstable cyclic endoperoxides. These endoperoxides are then converted into prostaglandins, prostacyclins, and thromboxanes.

Some of these prostanoids, like prostaglandins, are involved in the pathophysiology of inflammation, fever, and pain. The inhibition of the synthesis of these compounds is the reason for the therapeutic effect of flunixin.

Due to the involvement of prostaglandins in other physiological processes, the inhibition of cyclooxygenase also contributes to its gastrointestinal and renal side effects. Prostaglandins are part of the complex process involved in the development of endotoxic shock.

Pharmacokinetics Properties

In horses, after an intravenous injection at a dose of 1 mg/kg, rapid distribution is observed, and the elimination half-life is approximately 2 hours. It is primarily excreted in the urine in conjugated form.

In cattle, after an intramuscular injection at a dose of 2 mg/kg, the maximum concentration is achieved approximately 30 minutes after administration. In intravenous administration, rapid distribution and slow elimination are observed. The rate of binding to plasma proteins is high.

AREA OF USE/INDICATIONS

Horse: Used for reducing musculoskeletal pain and inflammation, as well as colic pain.

Cattle: Used for reducing clinical signs associated with respiratory system infections, along with appropriate antimicrobial treatment.

USAGE AND DOSAGE

Intravenous administration should be done slowly, and the product should be brought to body temperature before intravenous injection. Rapid intravenous injections are dangerous. Please read other sections.

Do not administer into an artery (arterial injection).

Horse:

For alleviating pain and inflammation in musculoskeletal disorders: It is administered intravenously at a dose of 1 mg/kg body weight/day (1 ml for every 50 kg body weight) for 1-5 days.

For reducing colic pain: it is administered intravenously at a dose of 1 mg/kg body weight/day (1 ml for every 50 kg body weight). This can be repeated 1-2 times if colic recurs.

Cattle:

It is administered intravenously or intramuscularly at a dose of 2 mg/kg body weight/day (2 ml for every 50 kg body weight) for 1-3 days. Doses greater than 20 ml should be applied in at least two different sites.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

The underlying cause of inflammation or colic should be treated with priority.

The recommended dose should not be exceeded.

Do not administer into an artery (arterial injection).

The use of this product in animals younger than 6 weeks or in older animals increases the risks related to the medication. If the use of the drug is unavoidable, the dose should be reduced, and careful clinical monitoring should be carried out.

Due to the general inhibition of prostaglandin synthesis by NSAIDs, in animals that have undergone general anesthesia, this product should not be administered before full recovery. In dehydrated, hypovolemic, and hypotensive animals, use should be avoided, except in cases of septic shock or endotoxemia.

Rarely, fatal shock may occur after intravenous administration of products containing propylene glycol. The drug should be administered slowly and at body temperature. If intolerance develops, the administration of the drug should be stopped, and shock treatment should be applied if necessary.

Due to its anti-inflammatory effect, clinical signs may be masked, and the potential resistance to the antibiotic being used may be overlooked.

Use immediately after birth may cause retention of the placenta (retention of secundines) by inhibiting uterine involution and the expulsion of fetal membranes.

NSAID-containing products may inhibit phagocytosis, so appropriate antimicrobial therapy may be required when treating inflammatory conditions related to bacterial infections.

Use during pregnancy: In laboratory animal studies, flunixin administered orally at maternotoxic doses in rabbits and rats, and intramuscularly in rats, has been shown to cause fetotoxicity and an increase in the pregnancy duration in rats.

The safety of the product in pregnant mares, stallions, and breeding bulls has not been established. Therefore, it should not be used in these animals. Safety has been demonstrated in cattle and pregnant and male pigs. It should not be used within 48 hours prior to parturition in these animals. (Refer to the contraindications and side effects section.)

The product can be used 36 hours after parturition, considering the veterinarian's risk/benefit

assessment and the risk of placental retention (as the product increases the retention rate).

ADVERSE EFFECTS

Bleeding, damage to the digestive system (irritation, gastric ulcers), vomiting, and especially kidney damage in dehydrated or hypovolemic animals may occur. Like other NSAIDs, rare or idiosyncratic hepatic and renal side effects may occur. If side effects are observed, the medication should be discontinued, and a veterinarian should be consulted.

Rarely, in cattle and horses, especially with rapid intravenous administration, fetal anaphylactic reactions (collapse) have been observed. It may cause changes in blood values.

In horses, after intravenous administration, diarrhea and the presence of blood in the feces have been reported.

In horses and cattle, intramuscular administration may cause a reaction at the injection site. The product shows a tocolytic effect by inhibiting the synthesis of prostaglandins responsible for initiating labor, which may delay labor or increase the risk of miscarriage.

Rapid intravenous administration may cause collapse.

Refer to the section on use during pregnancy, lactation, and the breeding period for further guidance.

DRUG INTERACTIONS

Low doses of acetylsalicylic acid, including, especially, its effects on the digestive system, should not be used in combination with other NSAID products or within 24 hours of their administration due to the increased risk of toxicity.

Some NSAID drugs bind highly to plasma proteins, and this property can increase the toxic effects of other drugs with similar characteristics. Flunixin increases the effects of warfarin and other drugs that bind to plasma proteins. Therefore, this should be considered when using them in concurrent treatment.

Due to the potential for increasing the toxicity and the risk of gastrointestinal ulceration in both products, it should not be used with corticosteroids.

Flunixin may reduce the effects of certain antihypertensive drugs, such as diuretics (ACE inhibitors), ACE inhibitors, and beta blockers, by inhibiting prostaglandin synthesis.

It should not be used concurrently with other drugs that have potential nephrotoxic effects, especially aminoglycosides. Flunixin may delay the renal excretion of drugs like aminoglycosides, increasing their toxicity.

It should not be used in combination with other veterinary medicinal products.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Flunixin is a nonsteroidal anti-inflammatory drug. Overdose is primarily associated with gastrointestinal toxicity. Ataxia and incoordination may be observed. In horses, intravenous administration of 3 times the recommended dose (3 mg/kg body weight) may result in a temporary increase in blood pressure. In cattle, intravenous administration of 3 times the recommended dose (6 mg/kg) has not shown any side effects.

WITHDRAWAL PERIODS

Meat: 31 days after intramuscular injection and 10 days after intravenous injection.

Milk: 36 hours (3 milkings) after intramuscular injection and 24 hours (2 milkings) after intravenous injection.

CONTRAINDICATIONS

Do not administer to animals with chronic musculoskeletal issues.

Do not administer to animals with liver, kidney, or heart disease.

Do not administer to animals with lesions in the digestive system (such as ulcers or bleeding).

Do not administer to animals with hemorrhagic disorders.

Do not administer to animals known to be sensitive to any ingredient in the composition or to other NSAIDs.

Do not administer in cases of colic associated with dehydration or ileus (intestinal obstruction).

Do not administer to cows within 48 hours prior to the expected birth, as there is a risk of miscarriage.

Do not administer to pregnant mares.

Refer to the section on use during pregnancy, lactation, and the breeding period for further guidance.

GENERAL WARNINGS

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

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

The product may cause sensitivity reactions. Individuals who are sensitive to anti-inflammatory products should not use the product. Intolerance reactions may reach serious levels. In case of skin contact, the area should be washed thoroughly with water and soap. If symptoms persist, medical treatment should be sought. In case of eye contact, the eyes should be washed with plenty of water, and medical treatment should be sought. To avoid oral exposure to the product, nothing should be eaten or drunk during application, and hands should be washed after use. In case of accidental ingestion, consult a doctor. In case of accidental self-injection, treatment should be sought at a healthcare facility with the product's leaflet and label.

STORAGE CONDITIONS AND SHELF LIFE

Before and after opening it should be stored in the original packages, protected from light, and stored below 25°C without placed in the refrigerator or freezer. The shelf life is 3 years. It should be consumed within 28 days after opening.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES

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

COMMERCIAL PRESENTATION FORM

20 ml, 50 ml, 100 ml and 250 ml amber-colored glass vials in boxes.

PLACE AND CONDITIONS OF SALE

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

APPROVAL DATE OF LEAFET: 06.01.2025

MARKETING AUTHORIZATION DATE AND NO: 22.10.2002 – 011/1093

NAME AND ADDRESS OF 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

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

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

Made in Türkiye

Label

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Horse: For the reduction of musculoskeletal pain, inflammation, and colic pain.

Cattle: Used to reduce clinical symptoms during respiratory system infections in conjunction with appropriate anti-infective treatment.

Do not administer into an artery (arterial injection).

Horse: 1 ml intravenously for every 50 kg body weight.

Cattle: 2 ml intravenously or intramuscularly for every 50 kg body weight.

For detailed information, please read the leaflet.

Drug residue withdrawal time (d.w.w.t):

Meat: 31 days for intramuscular injection, 10 days for intravenous injection.

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