

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Finadyne Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Flunixin (as meglumine) 50 mg/ml

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Phenol	5.0 mg
Sodium formaldehyde sulfoxylate	2.5 mg
Propylene glycol	207.2 mg
Edetate Disodium	
Sodium phosphate tribasic dodecahydrate	
Sodium hydroxide	
Water for injection	

Clear, colourless to light yellow solution.

PHARMACEUTICAL FORM

Solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs.

3.2 Indications for use for each target species

In Cattle:

For the antipyretic effect in acute inflammatory conditions.

In Horses:

For the alleviation of inflammation and pain associated with musculo-skeletal disorders.

For the alleviation of visceral pain associated with colic.

In Pigs: Sow mamillary metritis agalactia syndrome.

3.3 Contraindications

Do not use in animals suffering from cardiac, hepatic, or renal disease or where there is the possibility of gastro-intestinal ulceration or bleeding.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients listed in section 2.

Do not use if haematopoiesis or haemostasis is impaired.

Do not use in case of colic caused by ileus and associated with dehydration.

The safety of the veterinary medicinal product has been established in pregnant cows and sows.

Do not use the veterinary medicinal product within 48 hours before expected parturition in cows and sows.

The safety of the veterinary medicinal product has not been established in pregnant mares. Do not use during the whole of the pregnancy.

The safety of the veterinary medicinal product has not been established in bulls, stallions and boars intended for breeding. Do not use in breeding bulls, breeding stallions and breeding boars.

Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

Do not administer corticosteroids concurrently.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Inject slowly as life threatening symptoms of shock can occur due to the content of propylene glycol.

NSAIDs are known to have the potential to delay parturition through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition.

The use of the veterinary medicinal product in the immediate post-partum period may interfere with uterine involution and expulsion of foetal membranes resulting in retained placentae.

The veterinary medicinal product should have a temperature close to body temperature. Stop injection immediately after first symptoms of shock and start shock treatment if necessary.

Use of NSAID's in hypovolemic animals or animals with shock should be subject to a benefit-risk evaluation performed by the responsible veterinarian due to the risk of renal toxicity.

Use in very young (cattle, horses: less than 6 weeks old) as well as in old animals

may involve additional risks. If such treatment cannot be avoided, careful clinical observation is indicated. The underlying cause of pain, inflammation or colic should be determined and, when appropriate, antibiotic or re-hydration therapy should be given concurrently.

NSAIDs can cause phagocytosis inhibition and, therefore, in the treatment of inflammatory states associated with bacterial infections, appropriate concurrent antimicrobial therapy should be established.

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

This veterinary medicinal product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to non-steroidal anti-inflammatory drugs such as flunixin and/or to propylene glycol should avoid contact with the veterinary medicinal product. In case of hypersensitivity reactions seek medical advice and show the package leaflet or the label to the physician.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin or eyes. Wash hands after use. In case of accidental skin contact, wash affected area immediately with plenty of water.

In case of accidental eye contact, rinse eyes immediately with plenty of water. If skin and /or eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Accidental self-injection may cause pain and inflammation. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Laboratory studies in rats with flunixin have shown evidence of foetotoxic effects.

Pregnant women should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Special precautions for the protection of the environment:

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

3.6 Adverse events

Cattle:

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site reaction (such as injection site irritation and injection site swelling).
Rare (1 to 10 animals / 10,000 animals treated):	Liver disorder; Renal disorder (Nephropathy, Papillary necrosis) ¹ .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis (e.g. Anaphylactic shock, Hyperventilation, Convulsion, Collapse, Death) ² ; Ataxia ² ; Blood and lymphatic system disorder ³ , Haemorrhage; Digestive tract disorder (gastrointestinal irritation, gastrointestinal ulceration, digestive tract haemorrhage, nausea, blood in faeces, diarrhoea) ¹ ; Delay of parturition ⁴ , stillbirth ⁴ , retained placenta ⁵ ; Appetite loss.

¹ Particularly in hypovolaemic and hypotensive animals.

² After intravenous administration. At the onset of the first symptoms, administration should be stopped immediately and, if necessary, anti-shock treatment should be started.

³ Blood count abnormalities.

⁴ By a tocolytic effect induced by inhibition of the synthesis of prostaglandins, responsible for the initiation of parturition.

⁵ If the product is used in the period following parturition.

Horses:

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site reaction (such as injection site irritation and injection site swelling).
Rare (1 to 10 animals / 10,000 animals treated):	Liver disorder; Renal disorder (Nephropathy, Papillary necrosis) ¹ .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis (e.g. Anaphylactic shock, Hyperventilation, Convulsion, Collapse, Death) ² ; Ataxia ² ; Blood and lymphatic system disorder ³ , Haemorrhage; Digestive tract disorder (gastrointestinal irritation, gastrointestinal ulceration, digestive tract haemorrhage, nausea, blood in faeces, diarrhoea) ¹ ; Delay of parturition ⁴ , stillbirth ⁴ , retained placenta ⁵ ; Excitation ⁶ ; Muscle weakness ⁶ ; Appetite loss.

¹ Particularly in hypovolaemic and hypotensive animals.

² After intravenous administration. At the onset of the first symptoms, administration should be stopped immediately and, if necessary, anti-shock treatment should be started.

³ Blood count abnormalities.

⁴ By a tocolytic effect induced by inhibition of the synthesis of prostaglandins, responsible for the initiation of parturition.

⁵ If the product is used in the period following parturition.

⁶ May occur through accidental intra-arterial injection.

Pigs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site reaction (such as injection site skin discolouration, injection site pain, injection site irritation and injection site swelling) ¹ .
Rare (1 to 10 animals / 10,000 animals treated):	Liver disorder; Renal disorder (Nephropathy, Papillary necrosis) ² .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Blood and lymphatic system disorder ⁴ , Haemorrhage; Digestive tract disorder (gastrointestinal irritation, gastrointestinal ulceration, digestive tract haemorrhage, vomiting, nausea, blood in faeces, diarrhoea) ² ; Delay of parturition ⁵ , stillbirth ⁵ , retained placenta ⁶ ; Appetite loss.

¹ Resolves spontaneously within 14 days.

² Particularly in hypovolaemic and hypotensive animals.

⁴ Blood count abnormalities.

⁵ By a tocolytic effect induced by inhibition of the synthesis of prostaglandins, responsible for the initiation of parturition.

⁶ If the product is used in the period following parturition.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il/>

3.7 Use during pregnancy or lactation or lay

Pregnancy:

The safety of the veterinary medicinal product has been established in pregnant cows and sows. Do not use the veterinary medicinal product within 48 hours before expected parturition in cows and sows.

The safety of the veterinary medicinal product has not been established in pregnant mares. Do not use during the whole of the pregnancy.

Laboratory studies in rats have revealed fetotoxicity of flunixin after intramuscular administration at maternotoxic doses as well as an extension of the gestation period.

The veterinary medicinal product should be administered within the first 36 hours postpartum only following a benefit/risk assessment performed by the responsible veterinarian and treated animals should be monitored for retained placenta.

Fertility:

The safety of the veterinary medicinal product has not been established in bulls, stallions and boars intended for breeding. Do not use in breeding bulls, breeding stallions and breeding boars.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other. Do not administer corticosteroids concurrently.

Concurrent use of other NSAIDs or corticosteroids may increase the risk of gastro-intestinal ulceration.

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

Flunixin may decrease the effect of some antihypertensive drugs by inhibiting prostaglandin synthesis, such as diuretics, ACE inhibitors (angiotensin converting enzyme inhibitors) and β -blockers.

Concomitant administration of potentially nephrotoxic drugs (e.g., aminoglycoside antibiotics) should be avoided.

3.9 Administration routes and dosage

Cattle

2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin per kg) administered intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days.

Horses

By intravenous injection for musculo-skeletal disorders at the following rate:

1 ml per 45 kg bodyweight (1.1 mg flunixin/kg) once daily for up to 5 days according to clinical response.

By intravenous injection for colic at the following rate:

1 ml per 45 kg bodyweight (1.1 mg flunixin/kg) repeated once or twice if colic recurs.

For the treatment of endotoxaemia or septic shock associated with gastric torsion and with other conditions in which the circulation of blood to the gastro-intestinal tract is compromised: 0.25 mg/kg every 6-8 hours, by intravenous injection.

Pigs

2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

When intramuscular injection is used, the dose should be divided between two injection sites on either side of the neck.

In order to prevent excessive broaching of the rubber stopper, it is not recommended that the stopper is broached more than 25 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdose is associated with gastrointestinal toxicity. Ataxia and incoordination may also occur.

In case of overdose, symptomatic treatment should be administered.

Horse:

Foals administered an overdose of 6.6 mg flunixin/kg bodyweight (i.e., 5X the recommended clinical dose) had more gastrointestinal ulceration, greater cecal pathology and cecal petechiation scores than control foals. In horses, after intravenous injection of three times the recommended dose, a transient increase in blood pressure may be observed.

Cattle:

In cattle, intravenous administration of three times the recommended dose did not cause any adverse effects.

Pig:

Pigs treated with 11 or 22 mg flunixin/kg bodyweight (i.e., 5X or 10X the recommended clinical dose) had increased spleen weight. Discoloration at the injection sites that resolved over the time was observed with higher incidence or severity in pigs treated with higher doses.

In pigs, at 2 mg/kg twice daily, a painful reaction at the injection site and an increase in leukocyte counts were observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.

Cattle: 10 days from the last treatment.

Pigs: 15 days from the last treatment.

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle after 72 hours from the last treatment.

4 PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AG90

4.2 Pharmacodynamics

Flunixin meglumine is a non-steroidal anti-inflammatory drug with analgesic and antipyretic activity. Flunixin meglumine acts as a reversible non-selective inhibitor of cyclo-oxygenase (both COX 1 and COX 2 forms), an enzyme in the arachidonic acid cascade pathway which is responsible for converting arachidonic acid to cyclic endoperoxides. Consequently, synthesis of eicosanoids, important mediators of the inflammatory process involved in central pyresis, pain perception and tissue inflammation are reduced. Through its effects on the arachidonic acid cascade, flunixin also inhibits the production of

thromboxane, a potent platelet pro-aggregator and vasoconstrictor which is released during blood clotting. Flunixin exerts its antipyretic effect by inhibiting prostaglandin E2 synthesis in the hypothalamus. Although flunixin has no direct effect on endotoxins after they have been produced, it reduces prostaglandin production and hence reduces the many effects of the prostaglandin cascade. Prostaglandins are part of the complex processes involved in the development of endotoxic shock. Due to the involvement of prostaglandins in other physiological processes, COX inhibition would also be responsible for different adverse reactions, such as gastrointestinal or renal damage.

4.3 Pharmacokinetics

Following intravenous administration of flunixin meglumine to equines (horses and ponies) at a dose of 1.1 mg/kg, the drug kinetics fit a two-compartment model. It showed a rapid distribution (volume of distribution 0.16 l/kg), with a high proportion of binding to plasma proteins (greater than 99%). The elimination half-life was between 1 and 2 hours. An AUC_{0-15h} of 19.43 µg·h/ml was determined. The excretion took place rapidly, mainly through the urine, reaching the maximum concentration therein 2 hours after administration.

After 12 hours of intravenous injection, 61% of the administered dose had been recovered in the urine.

In cattle, after administering a dose of 2.2 mg/kg intravenously, maximum plasma levels of between 15 and 18 µg/ml were obtained 5-10 minutes after injection.

Between 2 and 4 hours later, a second plasma concentration peak was observed (possibly due to enterohepatic circulation), while at 24 hours the concentrations were less than 0.1 µg/ml.

Flunixin meglumine is rapidly distributed into organs and body fluids (with high persistence in inflammatory exudate), with a volume of distribution between 0.7 and

2.3 l/kg. The elimination half-life was approximately 4 to 7 hours.

Regarding excretion, this took place mainly through urine and feces. In milk, the drug was not detected, and in the cases where it was detected, the levels were negligible (<10 ng/ml).

In pigs, following intramuscular administration of 2.2 mg/kg flunixin meglumine, a maximum plasma concentration of about 3 µg/ml was detected approximately 20 minutes after injection.

The bioavailability, expressed as a fraction of the absorbed dose, was found to be 93%. The

Volume of distribution was 2 l/kg, while the elimination half-life was 3.6 hours. Excretion (most as unchanged drug) occurred primarily in the urine, although was also detected in the faeces.

Environmental properties

Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store below 25°C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Pack Sizes: 50 ml and 100 ml vials. Not all pack sizes may be marked.
Containers: Clear Type I glass vials
Closures: Butylic rubber stopper with flip-off cap.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of as toxic waste, do not throw to sewer.

6. MANUFACTURER

TriRx Segre, La Grindoliere, Zone Artisanale, Segre, 49500 Segre-en-Anjou Bleu, France

7. LICENSE HOLDER

Intervet Israel Ltd., Neve Ne'Eman Industrial Park, Hod HaSharon 45240

8. REGISTRATION NUMBER

083-99-91833-01

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