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MSD Animal Health UK Limited

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**Website:**www.msd-animal-health.co.uk

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**Finadyne® 50mg/ml Solution for Injection**

**Species:**Cattle, Horses and other equidae, Pigs

**Therapeutic indication:Pharmaceuticals: Anti-inflammatory preparations: Injections:** NSAIDs

**Active ingredient:**Flunixin Meglumine

**Product:**Finadyne® 50mg/ml Solution for Injection

**Product index:**Finadyne® 50mg/ml Solution for Injection

**Incorporating:**

**Qualitative and quantitative composition**

Each ml contains:

**Active substance:**

50 mg Flunixin equivalent to 83 mg Flunixin meglumine.

**Excipients:**

Phenol 5.0 mg

Sodium formaldehyde sulfoxylate 2.5 mg

Propylene glycol 207.2 mg

For a full list of excipients, see section “Pharmaceutical Particulars”.

**Pharmaceutical form**

Clear, colourless to light yellow solution, free from foreign matters.

**Clinical particulars**

**Target Species**

Cattle, horses and pigs.

**Indications for use**

Cattle

Adjunctive therapy in the treatment of bovine respiratory diseases, endotoxemia and acute mastitis.

Alleviation of acute inflammation and pain associated with musculoskeletal disorders.

Reduction of post-operative pain associated with dehorning in calves of less than 9 weeks.

Horses

Alleviation of acute inflammation and pain associated with musculoskeletal disorders.

Alleviation of visceral pain associated with colic.

Adjunctive therapy of endotoxemia due to or as a result of post-surgical or medical conditions or diseases that result in impaired blood circulation in the gastrointestinal tract.

Reduction of pyrexia

Pigs

Adjunctive therapy in the treatment of swine respiratory disease.

Adjunctive treatment of postpartum dysgalactia (Mastitis-Metritis-Agalactia) syndrome in sows.

Alleviation of acute inflammation and pain associated with musculoskeletal disorders.

Reduction of post-operative pain following castration and tail docking in sucking piglets.

**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.

Do not use if haematopoiesis or haemostasis is impaired.

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

**Special warning for each target species**

None.

**Special precautions for use**

Inject slowly as life threating 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.

**Operator warnings**

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.

**Adverse reactions**

Cattle:

| | |
|---|---|
| Uncommon (1 to 10 animals / 1,000 animals treated): | Injection site reaction (such as injection site irritatio |

| | |
|---|---|
| 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, Co |
| | Ataxia2; |
| | Blood and lymphatic system disorder3, Haemorrhage; |
| | Digestive tract disorder (gastrointestinal irritation, gastrointe haemorrhage, nausea, blood in faeces, diarrhoea)1; |
| | Delay of parturition4, stillbirth4, retained placenta5; Appetit |

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 irritatio |
| 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, Hyperventilati |
| | Ataxia2; |
| | Blood and lymphatic system disorder3, Haemorrhag |
| | Digestive tract disorder (gastrointestinal irritation, ga haemorrhage, nausea, blood in faeces, diarrhoea)1; |
| | Delay of parturition4, stillbirth4, retained placenta5; |
| | Excitation6; |
| | Muscle weakness6; 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 disco site irritation and injection site swelling) 1. |
| Rare (1 to 10 animals / 10,000 animals treated): | Liver disorder;<br>Renal disorder (Nephropathy, Papillary necrosis)2. |
| Very rare (<1 animal / 10,000 animals treated, including isolated reports): | Anaphylaxis (e.g. Anaphylactic shock, Hyperventilatio<br>Ataxia3;<br>Blood and lymphatic system disorder4, Haemorrhage;<br>Digestive tract disorder (gastrointestinal irritation, gast haemorrhage, vomiting, nausea, blood in faeces, diarr<br>Delay of parturition5, stillbirth5, retained placenta6; A |

1 Resolves spontaneously within 14 days.
2 Particularly in hypovolaemic and hypotensive animals.

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

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 adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

**Use during pregnancy or lactation**

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.

**Interaction**

Do not administer other NSAIDs concurrently or within 24 hours of each other.

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

Concurrent administration of potentially nephrotoxic drugs should be avoided.

**Amounts to be administered and administration route**

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.

*Amounts to be administered and administration route:*

Intramuscular and intravenous use in cattle.

Intramuscular use in pigs.

Intravenous use in horses.

**Cattle**

Adjunctive therapy in the treatment of bovine respiratory diseases, endotoxemia and acute mastitis and alleviation of acute inflammation and pain associated with musculoskeletal disorders

2.2 mg flunixin/kg bodyweight (2 ml per 45 kg) once daily via intramuscular or intravenous route. Repeat as necessary at 24-hour intervals for up to 3 consecutive days.

For intramuscular use, if dose volumes exceed 8 ml, it should be divided and injected into two or three sites. In case that more than three site are necessary, the intravenous route should be used.

Reduction of post-operative pain associated with dehorning in calves of less than 9 weeks

A single intravenous administration of 2.2 mg of flunixin per kg bodyweight (2 mL per 45 kg), 15-20 minutes before the procedure.

**Horses**

Alleviation of acute inflammation and pain associated with musculoskeletal disorders and reduction of pyrexia

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

Alleviation of visceral pain associated with colic

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

Adjunctive therapy of endotoxemia due to or as a result of post-surgical or medical conditions or diseases that result in impaired blood circulation in the gastrointestinal tract

0.25 mg flunixin/kg bodyweight every 6-8 hours or 1.1 mg flunixin/kg bodyweight once daily for up to 5 consecutive days.

**Pigs**

Adjunctive therapy in the treatment of swine respiratory disease, adjunctive treatment of postpartum dysgalactia (Mastitis-Metritis-Agalactia) syndrome in sows, alleviation of acute inflammation and pain associated with musculoskeletal disorders

2.2 mg flunixin/kg bodyweight (2 ml per 45 kg) once daily for up to 3 consecutive days. The injection volume should be limited to a maximum of 4 ml per injection site.

Reduction of post-operative pain following castration and tail docking in sucking piglets

A single administration of 2.2 mg of flunixin per kg bodyweight (0.2 mL per 4.5 kg), 15-30 minutes before the procedure.

Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.

To ensure a correct dosage, body weight should be determined as accurately as possible.

**Overdose**

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. Foals treated with 1.1 mg flunixin/kg bodyweight for 30 days intramuscularly, developed gastric ulceration, hypoproteinemia, and renal papillary necrosis. Renal crest necrosis was observed in 1 out of 4 horses treated with 1.1 mg flunixin/kg bodyweight for 12 days. 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.

**Withdrawal period**

**Cattle**

Meat and offal:

4 days (intravenous use).

31 days (intramuscular use).

Milk:

24 hours (intravenous use).

36 hours (intramuscular use).

**Pigs**

Meat and offal:

24 days (intramuscular use).

**Horses**

Meat and offal:

5 days (intravenous use).

Milk:

Not authorised for use in animals producing milk for human consumption.

**Pharmacological particulars**

**ATCvet code:** QM01AG90

**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.

**Pharmacokinetic particulars**

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 AUC0-15h 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. In cattle, after intramuscular administration of flunixin at a dose of 2 mg/kg, a maximum concentration is observed approximately 30 minutes after injection.

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.

**Pharmaceutical particulars**

**Excipients**

Phenol

Sodium formaldehyde sulfoxylate

Propylene glycol

Disodium edetate

Trisodium phosphate dodecahydrate E339

Sodium hydroxide

Water for injection

**Incompatibilties**

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

**Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

**Special Precautions for Storage**

This veterinary medicinal product does not require any special storage conditions.

**Immediate packaging**

Container: Clear Type I glass vial.

Closure: Chlorobutyl rubber stopper with Aluminium and plastic flip-off cap.

Pack sizes:

1 x 50 ml vial

6 x 50 ml vial

10 x 50 ml vial

1 x 100 ml vial

10 x 100 ml vial

1 x 250 ml vial

6 x 250 ml vial

Not all pack sizes may be marketed.

**Disposal**

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**Marketing Authorisation Holder (if different from distributor)**

Intervet International B.V., represented by MSD Animal Health UK Limited.

**Marketing Authorisation Number**

UK: Vm 06376/4088

**Significant changes**

**Date of the first authorisation or date of renewal**

Date of first authorisation 27 August 1987

Date of last renewal: 27 August 2007

**Date of revision of the text**

September 2025.

**Any other information**

**Legal category**

**Legal category:**POM-V

**GTIN**

**NOAH Compendium**

**GTIN description:**----

**GTIN:**----