

Veterinary medicine package leaflet

This medicine is dispensed with a veterinarian's prescription only
For use in animals only

1. Name, form and strength of the veterinary medicine

Finadyne Veterinary

50 mg/ml, solution for injection

2. Active ingredient

Flunixin (as meglumine) 50 mg/ml

Each 1 ml contains 50 mg flunixin.

A list of inactive ingredients and allergens is provided in section 13 – 'Additional Information'.

Clear, colourless to light yellow solution.

3. What is the medicine intended for?

Horses: For the alleviation of inflammation and pain associated with musculoskeletal disorders and for the alleviation of visceral pain associated with colic.

Cattle: An antipyretic for acute inflammatory conditions.

Pigs: Mammillary metritis agalactia syndrome in post-partum sows.

Therapeutic group: Non-steroidal anti-inflammatory drugs

4. Contraindications

- Do not use if you are sensitive (allergic) to the active substance or to any of the additional inactive ingredients the medicine contains.
- Do not use in animals suffering from cardiac disorders, Liver disorders or renal disorders or where there is the possibility of gastrointestinal ulceration or bleeding.
- Do not use in case of colic caused by ileus and associated with dehydration.
- Do not use if haematopoiesis or coagulation is impaired.
- 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.

5. Side effects

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 (incoordination) 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(incoordination) 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.
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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.

If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can report side effects to the Ministry of Health by following the link

'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

6. Target animals

Horses, cattle, pigs.

7. Method of administration and dosage

Horses

- For musculoskeletal disorders - 1 ml per 45 kg of body weight (equivalent to 1.1 mg of flunixin per kg) by intravenous (I.V.) injection once daily, for up to 5 days.
- For colic - 1 ml per 45 kg of body weight (equivalent to 1.1 mg of flunixin per kg) by intravenous (I.V.) injection. It should be given once or twice if colic recurs.
In the case of endotoxemia, or septic shock associated with gastric torsion, and other conditions where blood flow to the digestive system is compromised, 0.25 mg per 1 kg of body weight, every 6-8 hours by intravenous (I.V.) injection.

Cattle

2 ml per 45 kg of body weight (equivalent to 2.2 mg of flunixin per kg) by intravenous (I.V.) injection. Repeat as needed every 24 hours for up to 5 consecutive days.

Pigs

A one-time dose of 2 ml per 45 kg of body weight (equivalent to 2.2 mg of flunixin per kg) into the neck muscles (I.M.) combined with appropriate antibiotic treatment. The injection volume should not exceed 5 ml per injection site.

8. How to use this medicine

Horses: Intravenous injection (I.V.)

Cattle: Intravenous injection (I.V.)

Pigs: Intramuscular injection (I.M.)

9. Withdrawal period

Withdrawal period for slaughter

Cattle: 10 days after termination of treatment.

Pigs: 15 days after termination of treatment

Withdrawal period for milk

Cows: 72 hours after termination of treatment

10. Warnings

• Special warning

None.

• Special precautions for safe use of the medicine in the animal:

- Do not exceed the recommended dose.
- 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.

- Pregnancy and lactation of the treated animal

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 with other medicinal products and other forms of interactions

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 gastrointestinal 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.

- 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. 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.

- Major incompatibility

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

11. Storage instructions

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants.

Do not use the medicine after the expiry date (exp. date) which is stated on the package.

The expiry date refers to the last day of that month.

Store below 25°C. Do not freeze.

Use within 28 days from the opening date, but no later than the expiry date of the medicine.

12. Instructions for the disposal of unused product or waste materials

Do not throw away medicine via wastewater or household waste. Ask the veterinarian how to destroy unused medicines in order to protect the environment. These measures should help to protect the environment.

13. Additional information

- In addition to the active ingredient, this medicine also contains:
Propylene glycol, phenol, sodium phosphate tribasic dodecahydrate, sodium formaldehyde sulfoxylate, edetate disodium, sodium hydroxide, water for injection.
- What the medicine looks like and contents of the pack: carton box with 50 ml or 100 ml vials.
Not all pack sizes may be marketed.
- **Registration holder's name and address:** Intervet Israel Ltd., Neve Ne'Eman Industrial Park, Hod Hashron 45240.
- **Manufacturer's name and address:**
TriRx Segre, La Grindoliere, Zone Artisanale, Segre, 49500 Segre-en-Anjou Bleu, France.

Revised in November 2025.

Registration number of the medicine in the Ministry of Health National Drug Registry: 083-99-91833-01