SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/g Oral Paste

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of the oral paste contains:

Active substance:
Flunixin 50 mg
(as flunixin meglumine 83 mg)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Propylene glycol	100 mg
Carmellose sodium	
Maize starch	
Water, purified	

White to off-white paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

3.3 Contraindications

Do not exceed the stated dose or duration of treatment.
Do not use in animals suffering from cardiac, hepatic or renal disease, or where there is the possibility of gastrointestinal ulceration or bleeding.
Do not use in cases of hypersensitivity to the active substance.
Do not administer steroidal or other non-steroidal anti-inflammatory drugs concurrently or within 24 hours of each other.
Do not use in hypovolaemic animals except in the case of endotoxaemia or septic shock.

3.4 Special warnings

Non-steroidal anti-inflammatory drugs are not permitted substances under the rules of racing and under rules covering other competitive events. The Royal College of Veterinary Surgeons has given guidance to the Veterinary profession regarding the use of anti-inflammatory drugs in competing horses. It states that if a veterinarian recommends the discontinuation of any such drug not less than eight days before racing he should feel sure he has catered for all but the most exceptional case.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use in animals less than 6 weeks of age or in aged animals may involve additional risk.
If such use cannot be avoided animals may require a reduced dosage and careful clinical management.
In animals undergoing general anaesthesia it is preferable to wait until they are fully recovered before the veterinary medicinal product is administered.
NSAIDs can cause inhibition of phagocytosis. During use in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be administered.
Avoid use in dehydrated, hypovolaemic or hypersensitive animals as there is a potential risk of increased renal toxicity.
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact with eyes and direct contact with skin. In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice and show the package leaflet or the label to the physician.

The veterinary medicinal product may cause reactions in sensitive individuals.
Reactions may be serious.
People with known hypersensitivity to non-steroidal anti-inflammatory products, should avoid handling the veterinary medicinal product.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product during application.

Wash hands and exposed skin after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction (e.g., allergic skin reaction, anaphylaxis)

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.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of potentially nephrotoxic drugs should be avoided.

Some NSAIDs may be highly bound to plasma proteins and may compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations which can lead to toxic effects.

3.9 Administration routes and dosage

Oral use.

1.1 mg flunixin per kg bodyweight once daily for up to 5 days according to clinical response.
Each 10 g syringe is sufficient for one day’s treatment for a 454 kg (1000 lb.) horse. The syringe is calibrated in 100 kg increments to facilitate dosing of horses of different weights.

Prior to first use, the syringe must be primed. Set the ring on the graduated syringe plunger to the zero (0) position. Remove the cap and press the plunger to remove air. Discard any small volume of paste that may be expelled. The syringe is now ready for use.

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

Overdosage studies in the target species have shown the product to be well-tolerated. Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdosage is associated with gastrointestinal toxicity.

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

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AG90.

4.2 Pharmacodynamics

Flunixin meglumine is a potent non-steroidal, non-narcotic analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic activities.

4.3 Pharmacokinetics

None known.

Environmental properties

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.
Do not freeze.
Replace cap after use.
Keep syringes in the outer box.
Store syringes in an upright position.

5.4 Nature and composition of immediate packaging

White low density polyethylene syringes with white linear polyethylene graduated plungers and white low density polyethylene caps.

Pack size: Cardboard box containing 6 x 10 g syringes.

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

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4089

8. DATE OF FIRST AUTHORISATION

02 February 1989

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

September 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall

Approved: 04 December 2025