SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/g Oral Paste

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:
Active substance:
Flunixin 50 mg as flunixin meglumine 83 mg

Excipients:
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral paste.
White to off-white paste.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals:
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 medicinal product to the animals:
Avoid contact with eyes and direct contact with skin. Gloves should be worn during application.
In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
The product may cause reactions in sensitive individuals. If you have known hypersensitivity to non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.
Wash hands and exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions (allergic skin reactions, anaphylaxis) may occur after administration of the veterinary medicinal product in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids
ATCvet Code: QM01AG90

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

None known.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Carmellose sodium
Maize starch
Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

6.4 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.

6.5 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: Carboard box with 6 x 10 g syringes.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4089

9. DATE OF FIRST AUTHORISATION

02 February 1989

10. DATE OF REVISION OF TEXT

December 2024

Approved 10 December 2024
Gavin Hall