SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 5 % w/w Oral Paste

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	**% w/w**
Flunixin	5.0
(as Flunixin meglumine	8.3

For 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

Horse

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 Contra-indications

Do not exceed the stated dose or duration of treatment.
Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, or where there is hypersensitivity to the product.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Do not use in hypovolaemic animals except in the case of endotoxaemia or septic shock.
Avoid use in dehydrated, hypovolaemic or hypersensitive animals as there is a potential risk of increased renal toxicity.

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

(i) 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.
It is preferable that flunixin is not administered to animals undergoing general anaesthesia until fully recovered.
NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

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

(ii) 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)

None known.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant mares. Safety studies in pregnant mares have not been conducted.

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

For oral administration only.

1.1mg flunixin per kg bodyweight once daily for up to 5 days according to clinical response.

Each syringe is sufficient for one day's treatment for a 454kg (1000 lb.) horse. The syringe is calibrated in 100 kg increments to facilitate dosing of horses of different weights.

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
ATC 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Carmellose sodium

Maize Starch
Purified water

6.2 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.

6.5 Nature and composition of immediate packaging

10g or 30g natural low density white polyethylene syringe barrel and white polypropylene dial-a-dose plunger with low density polyethylene cap and plunger seal.

Not all pack sizes may be marketed.

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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4599

9. DATE OF FIRST AUTHORISATION

02 February 1989

10. DATE OF REVISION OF TEXT

April 2021

Approved: 28/04/21