SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	**% w/v**
Flunixin (as Flunixin Meglumine)	5.0
Excipients:	
Phenol (preservative)	0.50

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses and pigs.

4.2 Indications for use, specifying the target species

In Cattle:
For the control of acute inflammation associated with respiratory disease.
Finadyne has also been shown to have some benefit in the treatment of experimental acute bovine pulmonary emphysema (Fog Fever).
Finadyne Solution may be used as adjunctive therapy in the treatment of acute mastitis.

In Horses:
For the alleviation of inflammation and pain associated with musculo-skeletal disorders.
For the alleviation of visceral pain associated with colic in the horse.

In Pigs:
For use as an adjunctive therapy in the treatment of swine respiratory diseases.

4.3 Contra-indications

Do not exceed the stated dose or the duration of treatment.
Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is hypersensitivity to the product.
Do not use the product within 48 hours before expected parturition in cows.
ster to pregnant mares.

Do not administer to pregnant sows, gilts at mating and in breeding boars.

4.4 Special warning for each target species

Non-steroidal, anti-inflammatory drugs are not permitted under the rules of Racing and under rules covering other competitive events.
The Royal College of Veterinary Surgeons has given advice 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 that he has catered for all but the most exceptional case".
Do not exceed the recommended dose or duration of treatment.

4.5 Special precautions for use

i) Special precautions for use in animals

Avoid intra-arterial injection.
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 product in the immediate post-partum period may interfere with uterine involution and expulsion of foetal membranes resulting in retained placentae. See also section 4.7.
Use in any animal 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.
Do not use in hypovolaemic animals except in the case of endotoxaemia or septic shock.
It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.
The cause of colic should be determined and treated with concurrent therapy.
The product should not be used in piglets weighing less than 6 kg.

ii) Special precautions to be taken by the person administering the product to the animal

Avoid contact with skin or eyes.
In case of skin contact, wash exposed area with water.
In case of eye contact, wash eyes thoroughly with clean water and seek medical advice.
Take care against accidental self injection.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID). Untoward effects include gastro-intestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage.

In pigs transient irritation may occur at the injection site, this resolves spontaneously within 14 days.

4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating cattle.
The product should only be administered within the first 36 hours post-partum following a benefit/risk assessment performed by the responsible veterinarian and treated animals should be monitored for retained placentae.
Do not use in pregnant mares or pregnant sows. Safety studies in pregnant mares and pregnant sows have not been conducted.

4.8 Interaction with other medicinal products and other forms of 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.

4.9 Amounts to be administered and administration route

Cattle
2ml per 45kg bodyweight (equivalent to 2.2mg flunixin per kg) administered intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days.

Horses
By intravenous injection for musculo-skeletal disorders at the following rate:
1ml per 45kg bodyweight (1.1mg flunixin/kg) once daily for up to 5 days according to clinical response.

By intravenous injection for colic at the following rate:
1ml per 45kg bodyweight (1.1 mg flunixin/kg) repeated once or twice if colic recurs.
For the treatment of endotoxaemia or septic shock associated with gastric torsion and with other conditions in which the circulation of blood to the gastro-intestinal tract is compromised: 0.25mg/kg every 6-8 hours, by intravenous injection.

Pigs
2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.
When intramuscular injection is used, the dose should be divided between two injection sites on either side of the neck.

In order to prevent excessive broaching of the rubber stopper, it is not recommended that the stopper is broached more than 25 times.

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. Concurrent use of nephrotoxic drugs should be avoided.

4.11 Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.
Cattle: 5 days from the last treatment.
Horses: 7 days from the last treatment.
Pigs: 22 days from the last treatment.
Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle after 24 hours from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium phosphate tribasic dodecahydrate
Edentate disodium
Sodium formaldehyde sulfoxylate Propylene glycol
Sodium hydroxide
Water for injection

6.2 Major incompatibilities

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 potential nephrotoxic drugs should be avoided.

6.3 Shelf-life

3 years
Following withdrawal of the first dose, use within 28 days.
Discard unused material.

6.4 Special precautions for storage

Do not store above 25°C.
Do not freeze.

6.5 Nature and composition of immediate packaging

Pack Sizes: 50 ml and 100 ml vials.
Containers: Clear Type I glass vials, moulded.
Closures: Chlorobutyl rubber stopper with flip-off cap.

6.6 Special precautions for the disposal of unused product or waste material

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
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4582

9. DATE OF FIRST AUTHORISATION

27 August 1987

10. DATE OF LAST REVISION

April 2021

Approved: 28/04/21

D Austin