1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/ml Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Flunixin (as flunixin meglumine) 50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium phosphate dodecahydrate	4.0 mg
Phenol	5.0 mg
Disodium edetate	
Sodium formaldehydesulfoxylate	
Propylene glycol	207.2 mg
Sodium hydroxide	

Clear, colourless to light yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses and pigs.

3.2 Indications for use for each target species

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

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

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

3.3 Contraindications

Do not use the veterinary medicinal product within 48 hours before expected parturition in cows.
Do not administer to gilts at mating, breeding boars or piglets less than 6 kg bodyweight.
Do not use in animals suffering from cardiac, hepatic or renal disease or where there is the possibility of gastro-intestinal ulceration or bleeding.
Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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. See also section 3.7.

Inject slowly as life threating symptoms of shock can occur due to the content of propylene glycol.
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 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 exceed the stated dose or the duration of treatment.
Avoid intra-arterial injection.

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:
People with known hypersensitivity to flunixin should avoid contact with the veterinary medicinal product.
Avoid contact with skin or eyes. In case of skin contact, wash exposed area with water.
In case of eye contact, rinse eyes immediately with copious amounts of clean water, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

3.6 Adverse events

Horses:

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site reaction
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[1]; Renal failure[2]; Gastrointestinal irritation, Gastrointestinal ulceration; Ataxia

[1] May result in collapse following intravenous injection, fatalities have been reported.
[2] Particularly in dehydrated or hypovolaemic animals.

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[1]; Renal failure[2]; Gastrointestinal irritation, Gastrointestinal ulceration; Ataxia

[1] May result in collapse following intravenous injection, fatalities have been reported.
[2] Particularly in dehydrated or hypovolaemic animals.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[1]; Renal failure[2]; Gastrointestinal irritation, Gastrointestinal ulceration; Ataxia Injection site irritation[3]

[1] May result in collapse following intravenous injection, fatalities have been reported.
[2] Particularly in dehydrated or hypovolaemic animals.
[3] Resolves spontaneously within 14 days.

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 the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Post marketing studies in cattle have indicated that the use of the veterinary medicinal product within the first 36 hours post-partum leads to an increased incidence of retained placentae. The veterinary medicinal 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 or pregnant sows have not been conducted.

3.8 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.

3.9 Administration routes and dosage

To ensure a correct dosage, body weight should be determined as accurately as possible.

Cattle:
2 ml per 45 kg body weight (equivalent to 2.2 mg flunixin per kg) administered intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days. The cause of the acute inflammatory condition should be determined and treated with concurrent therapy.

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

By intravenous injection for colic at the following rate:
1 ml per 45 kg body weight (equivalent to 1.1 mg flunixin/kg) repeated once or twice if colic recurs. During clinical trials, approximately 10 % of the horses required one or two additional treatments. The cause of colic should be determined and treated with concurrent therapy.

Pigs:
2 ml per 45 kg body weight (equivalent to 2.2 mg flunixin per kg) once by intramuscular injection in the neck. The veterinary medicinal product should be administered as adjunctive therapy in conjunction with a suitable course of antibacterial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

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

Overdosage studies in the target species have shown the veterinary medicinal product to be well-tolerated.
Overdosage is associated with gastrointestinal toxicity.
In case of overdose symptomatic treatment should be initiated.

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

Cattle:
Meat and offal: 7 days.
Milk: 36 hours.

Horses:
Meat and offal: 7 days.
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 24 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AG90.

4.2 Pharmacodynamics

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

Horses:
Intravenous injection for musculo-skeletal disorders: Studies show onset of activity within two hours. Peak response occurs within 12 to 16 hours, and the duration of activity is 24 to 36 hours.

Intravenous injection for the alleviation of visceral pain associated with equine colic: Clinical studies have shown that, in many cases, pain is alleviated within 15 minutes.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Pack size: 50 ml and 100 ml.
Containers: Clear Type I glass vials, moulded.
Closure: Chlorobutyl rubber stopper with aluminium and plastic flip-off cap.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/228/001

8. DATE OF THE FIRST AUTHORISATION

Date of first authorisation: 01 October 1989.

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database*:* (https://medicines.health.europa.eu/veterinary).

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