# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/ml Solution for Injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

| | |
|---|---|
| Active Substance | |
| Flunixin<br>(as Flunixin Meglumine) | 50 mg |
| Excipients | |
| Phenol | 5 mg |
| Sodium Formaldehyde Sulfoxylate | 2.5 mg |

For a 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.
The product has also been shown to have some benefit in the treatment of experimental acute bovine pulmonary emphysema (Fog Fever).
The product 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 Contraindications

Do not use the product within 48 hours before expected parturition in cows.
Do not administer to pregnant mares or pregnant sows.
Do not administer to gilts at mating, breeding boars or piglets less than 6 kg bodyweight.
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.

### 4.4 Special warnings for each target species

None.

**4.5 Special precautions for use**

**Special precautions for use in animals**
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.
Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Do not exceed the stated dose or the duration of treatment.
Avoid intra-arterial injection.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**
Direct contact with the skin should be kept to a minimum. Flunixin meglumine is irritating to the eye. Avoid contact with eyes. If contact occurs, rinse immediately with clean running water. 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. However, these effects are rarely reported for this product in actual use.
There are occasional reports of injection site reactions in horses.
Anaphylactic-type reactions have been reported in both horses and cattle which may result in collapse following intravenous injection and on rare occasions, fatalities have been reported.

**4.7 Use during pregnancy, lactation or lay**

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

**4.8 Interaction with other medicinal products and other forms of interactions**

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**
2 ml per 45 kg bodyweight (equivalent to 2.2 mg 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:
1 ml per 45 kg bodyweight (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 bodyweight (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**
2ml per 45kg bodyweight (equivalent to 2.2mg flunixin per kg) once by intramuscular injection. The 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.

**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(s)**

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

Horses
Meat and offal: 7 days.

Pigs
Meat and offal: 24 days.

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids; Flunixin.
ATCvet code: QM01AG90.

**5.1 Pharmacodynamic properties**

Flunixin meglumine is a potent, 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
Disodium edetate dihydrate
Sodium formaldehyde sulfoxylate
Propylene glycol
Sodium hydroxide (for pH adjustment)
Water for injections

**6.2 Major incompatibilities**

None known.

**6.3 Shelf-life**

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

**6.4 Special precautions for storage**

Store below 25 °C.
Do not freeze.

**6.5 Nature and composition of immediate packaging**

Pack size: 50ml and 100ml
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.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

**7 MARKETING AUTHORISATION HOLDER**

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA10996/228/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 October 1989
Date of last renewal: 30 September 2009

**10 DATE OF REVISION OF THE TEXT**

June 2019