SUMMARY OF PRODCUT CHARASTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Finadyne Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Flunixin (as meglumine) 50 mg/ml

Excipients:
Phenol (preservative) 5 mg/ml

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 antipyretic effect in acute inflammatory conditions.

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

In Pigs: Sow mamilliary metritis agalactia syndrome.

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.
Do not administer to pregnant mares.
Do not administer to pregnant sows, gilts at mating and in breeding boars.
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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.
Inject slowly as life-threatening symptoms of shock can occur due to the content of propylene glycol. The product should have a temperature close to body temperature. Stop injection immediately if first symptoms of shock occur and start treatment for shock if necessary.
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.
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.

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.

Anaphylactic-type reactions have been reported in horses and cattle, resulting in collapse following intravenous injection. Such reactions, on very rare occasions have been life-threatening in spontaneous pharmacovigilance reports.

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).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

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

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.
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: 0.25 mg/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: 10 days from the last treatment.
Pigs: 15 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 72 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.

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
Phenol
Sodium phosphate tribasic dodecahydrate
Sodium Formaldehyde sulfoxylate
Edetate Disodium
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

The expiry date of the product is indicated on the packaging materials.
Following withdrawal of the first dose, use within 28 days.
Discard unused material.

6.4. Special precautions for storage

Store below 25°C.
Do not freeze.

6.5. Nature and composition of immediate packaging

Pack Sizes:	50 ml and 100 ml vials. Not all pack sizes may be marked.
Containers:	Clear Type I glass vials
Closures:	Butylic 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 as toxic waste, do not throw to sewer.

7. MANUFACTURER

TriRx Segre, La Grindoliere, Zone Artisanale, Segre, 49500 Segre-en-Anjou Bleu, France

8. LICENSE HOLDER

Intervet Israel Ltd., Neve Ne'Eman Industrial Park, Hod HaSharon 45240

9. REGISTRATION NUMBER

083-99-91833-01

Revised in November 2023 according to MOHs guidelines.