Consumer Package Insert for Veterinary Medicinal Product

This product is marketed with a veterinarian's prescription only
For animal use only

1. NAME OF THE VETERINARY MEDICINAL PRODUCT, ITS FORM AND STRENGTH

Finadyne Veterinary
Solution for Injection

2. ACTIVE INGREDIENT/S:

Flunixin (as meglumine) 5.0% w/v

Preservative: Phenol 0.50% w/v

A list of inactive ingredients is detailed in section 13 - "Further Information".

3. WHAT IS THE MEDICINE INTENDED FOR:

Horses: For the alleviation of inflammatory pain associated with musculoskeletal disorders and for the alleviation of visceral pain associated with colic.
Cattle: As an antipyretic for respiratory disease in cattle.
Pigs: Mammilliary metritis agalactia syndrome.

4. CONTRAINDICATIONS:

- Do not use in case of sensitivity to any of the ingredients.
- Do not exceed the recommended dose or the duration of treatment.
- Do not use in case of cardiac, hepatic or renal diseases.
- Do not use in case of possible gastro-intestinal ulceration or bleeding.
- Do not administer to pregnant mares.
- Do not treat pregnant sows or those intended for breeding.
- Do not use in cattle within 48 hours preceding expected parturition time.

5. SIDE EFFECTS:

Finadyne Veterinary is a medicine from the NSAIDs - non-steroidal anti-inflammatory drug group. Untoward effects can include digestive system irritation, peptic ulcers, and, in dehydrated or hypovolemic (low plasma level) animals, there is a risk of renal damage.
In pigs local irritation may occur at the injection site. This effect resolves spontaneously within 14 days.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

6. TARGET ANIMALS:

Horses, cattle, pigs.

7. METHOD OF ADMINISTRATION AND DOSAGE:

Horses:
- For muscle/skeletal disorders - 1 ml per 45 kg of body weight (equivalent to 1.1 mg of flunixin per kg) by intravenous (I.V.) injection once daily, for up to 5 days.

- For colic - 1 ml per 45 kg of body weight (equivalent to 1.1 mg of flunixin per kg) by intravenous (I.V.) injection. It should be given once, or twice if colic recurs.
- In the case of endotoxemia, or septic shock associated with gastric torsion, and other conditions where blood flow to the digestive system is compromised, 0.25 mg per 1 kg of body weight, every 6 to 8 hours by intravenous (I.V.) injection.

Cattle:
2 ml per 45 kg of body weight (equivalent to 2.2 mg of flunixin per kg) by intravenous (I.V.) injection. Repeat as needed every 24 hours for up to 5 consecutive days.

Pigs:
A one-time dose of 2 ml per 45 kg of body weight (equivalent to 2.2 mg of flunixin per kg) into the neck muscles (I.M.) combined with appropriate antibiotic treatment. The injection volume should not exceed 5 ml per injection site.

8. ADMINISTRATION OF MEDICINAL PRODUCT:

Horses: Intravenous injection (I.V.)
Cattle: Intravenous injection (I.V.)
Pigs: Intramuscular injection (I.M.)

9. WITHDRAWAL PERIOD:

Withdrawal period for slaughter:
Cattle: 10 days after termination of treatment.
Pigs: 15 days after termination of treatment
Withdrawal period for milk:
Cows: 72 hours after termination of treatment.

10. PRECAUTIONS:

♦ Special precautions regarding use in the target animal

- Do not use in case of hypovolemia (low plasma volume) except in cases of endotoxemia or septic shock.
- Administration is not recommended in animals undergoing general anesthesia until complete recovery.
- Check the cause of colic and treat it simultaneously.
- Avoid treatment if cattle are receiving kidney medication.
- There is a risk in injecting animals under the age of 6 weeks or in older animals. If use of the medicine is essential, it may be necessary to reduce the dosage.
- Avoid subcutaneous or intra-arterial injection.
- Do not use in small pigs weighing less than 6 kg.
- NSAIDs (non-steroidal anti-inflammatory drugs) are known to have the potential to delay the parturition process by inhibiting prostaglandins that are important in the progression of parturition. The use of the medicine immediately after birth may interfere with uterine involution and expulsion of the placenta resulting in a retained placentae. See also the section "Pregnancy and lactation."

♦ Special precautions regarding the safety of the person handling the preparation

- Avoid contact of the product with the skin and eyes.
- In case of contact with the skin - Rinse the area with water.
- In case of contact with the eyes - Rinse your eyes well with clean water and seek medical advice.
- Be careful of self-injection.
- Wash your hands after use.

♦ Pregnancy and lactation

- The medicine is suitable for use in pregnant or lactating cows.
- The use of the medicine within 36 hours of birth, should be the responsibility of a veterinarian, while monitoring and examining the treated animal in order to rule out retained placentae.
- Do not use in pregnant mares and sows. Safety studies in pregnant mares and sows have not been conducted.

♦ Interactions with other medicines and other forms of interactions

- Do not administer other NSAIDs during treatment. If it is necessary, wait 24 hours.
- Some NSAIDs are bound in high concentrations to plasma proteins and compete with other medicines that bind in the same way, which can lead to toxic effects.
- Concurrent administration of other nephrotoxic medicines (that have potential for damaging the kidneys) should be avoided.

♦ Overdose

Overdosage studies in the target animals have shown the medicine to be well-tolerated. Overdosage is associated with digestive system toxicity. Concurrent use of nephrotoxic medicines (that have potential for damaging the kidneys) should be avoided.

♦ Major Incompatibility

See section "Interactions with other medicines and other forms of interactions".

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:**
  Store at a temperature below 25°C. Do not freeze.
  Use within 28 days from the opening date.

12. INSTRUCTIONS FOR THE DISPOSAL OF THE PRODUCT/UNUSED PRODUCT AFTER USE:

Do not discard any residue of medicines into the wastewater or waste bin. Ask the veterinarian how to dispose of medicinal residues in order to protect the environment.

13. FURTHER INFORMATION:

- In addition to the active ingredient, the medicine also contains:
  Propylene glycol, Phenol, Sodium phosphate tribasic dodecahydrate, Sodium formaldehyde sulfoxylate, Edetate disodium, Sodium hydroxide, Water for Injection.

- What does the medicine look like and what are the contents of the package:
  50 ml, 100 ml vials.

- Manufacturer name and address:
  TriRx Segre, La Grindoliere, Zone Artisanale, Segre, 49500 Segre-en-Anjou Bleu, France.

- License holder name and address: Intervet Israel Ltd.,
  Neve Ne'Eman Industrial Park,
  Hod Hasharon 45240

Revised in February 2021 according to MOHs guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
083-99-91833-01