

This leaflet has been reviewed and approved by the ministry of health: 13.1.2020

SUMMARY OF PRODUCT CHARACTERISTICS
Veterinarian Prescription only medicine
For animal use only

1. NAME FORM AND STRENGTH OF THE VETERINARY MEDICINE

Flunixin Solution for Injection Comex Veterinary, 50mg/ml, I.M, I.V

2. ACTIVE INGREDIENTS

Each ml contains:

Flunixin (as Meglumine) 50 mg

Excipients:

Phenol 5 mg/ml (preservative)

Sodium Formaldehyde Sulphoxylate Dihydrate 2.5 mg/ml (anti oxidant)

For a full list of excipients, see section 13 "further information"

3. Indications for use

Horses:

For the alleviation of inflammation and pain associated with musculo-skeletal disorders especially in acute and chronic stages.

For the alleviation of visceral pain associated with colic.

Cattle:

Control of acute inflammation associated with respiratory disease.

Therapeutic Group: NSAID- non steroidal anti-inflammatory drug

4. Contraindications

Do not use where there is hypersensitivity to the product or to one of the excipients.

Do not exceed the stated dose or the duration of treatment.

Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease

Use is contra-indicated in animals where there is the possibility of gastro-intestinal ulceration or bleeding.

Do not administer to pregnant mares.

Do not use the product within 48 hours before expected parturition in cows.

5. Adverse reactions (frequency and seriousness)

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

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.it) which refers to the online form for reporting

adverse events, or by entering the link:

<https://sideeffects.health.gov.il>

6. Target Species:

Cattle, Horses

7. Amounts to be administered and administration route

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.

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 (1 ml per 200kg bodyweight) every 6-8 hours, by intravenous injection.

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.

8. How to use the preparation:

Cattle: For intravenous administration (I.V)

Horses: for intravenous administration (I.V) can be used intramuscular (I.M) in horses.

9. Withdrawal period

Cattle: Meat: 10 days.

Milk: 72 hours.

10. Special warnings and precautions for use:

• Special precautions for use in animals:

- 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.
- 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.

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 for pregnancy and lactating.

- Special precautions to be taken by the person administering the veterinary medicinal product to animals:
 - 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.
- 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.
- 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
- Overdose:

Overdosage studies in the target species have shown the product to be well-tolerated. Overdosage is associated with gastrointestinal toxicity. Concurrent use of nephrotoxic drugs should be avoided.

11. **Storage instructions**

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.
- Storage conditions: Store below 25°C.
- Shelf-life after first opening the immediate packaging: 28 days. Remedies should be destroyed after 28 days.

12. **Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste. Do not dispose of sewage.

13. **FURTHER INFORMATION:**

In addition to the active ingredient the product also contains:

Phenol; Sodium Formaldehyde Sulphoxylate Dihydrate; Disodium Edetate Dihydrate; Propylene Glycol; Sodium Hydroxide; Hydrochroic Acid; Water for

Injection

Pharmaceutical form:

- A clear aqueous solution for injection. Packed in a 100 ml volume vial

Registration holder: :Comex Ltd, Nablus Rd. No.1, POB 19943, Jerusalem 97200

Manufacturer: Norbrook Laboratories Limited , Camlough Road, Newry, Co. Down
BT35 6JP, Northern Ireland, UK

Product registration number: 081-88-92251-00

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