Veterinary Medicine User Leaflet

Veterinarian Prescription Only Medicine

For Animal Use Only

1. NAME AND FORM OF THE VETERINARY MEDICINE:

Hexasol Veterinary, Solution for Injection

2. ACTIVE INGREDIENTS:

Each 1 ml of the medicine contains:

Oxytetracycline (as dihydrate)	*300 mg*
Flunixin (as flunixin meglumine)	*20 mg*

The medicine also contains the excipient:

Sodium Formaldehyde Sulphoxylate	0.4% w/v

For a full list of excipients, see section 13 “Further Information”.

3. Indications for use:

Hexasol Veterinary is used in the treatment of disease caused by microorganisms sensitive to oxytetracycline where anti-inflammatory, anti-pyretic and anti-bacterial effect is required.

Therapeutic group: Antibacterial, anti-inflammatory non-steroidal drug.

4. Contraindications:

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding or where there is hypersensitivity to the product.

Avoid use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

Do not administer other NSAIDs concurrently, or within 24 hours of each other.

Concurrent use of potentially nephrotoxic drugs should be avoided.

Do not exceed the stated dose or duration of treatment.

5. Adverse reactions:

The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.

Although the product is well tolerated, occasionally a local reaction of a transient nature may be observed.

Hypersensitivity reactions (collapse) may occur very rarely.

Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening.

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.il), which refers to the online form for reporting adverse events, or by entering the link: https://sideeffects.health.gov.il

6. Target species:

Cattle

7. Amount to be administered and administration route:

Indicated for deep intramuscular administration to cattle.

The recommended dosage is 1 ml per 10 kg bodyweight (equivalent to 2 mg/kg flunixin and 30 mg/kg oxytetracycline) on a single occasion.

8. How to use the product:

Maximum volume per injection site: 15ml.

If concurrent treatment is administered use a separate injection site.

Additional therapy with an NSAID may be administered after 24 hours if required.

Avoid the introduction of contamination.

9. Withdrawal period:

Cattle: Meat and offal: 28 days.

Not for use in cattle producing milk for human consumption.

10. Warnings:

- Special precautions regarding the use of the medicine for the target animal**:**

  None known.
- Special safety precautions regarding the use of the medicine in animals:

  Avoid intra-arterial injection.

  Use in any animals 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.

  It is preferable that prostaglandin inhibiting drugs are not administered to animals undergoing general anaesthesia until fully recovered.
- Special precautions to be taken by the person administering the product to the animals:

  Avoid eye contact and direct contact with skin.

  To avoid possible sensitisation reactions, avoid contact with skin. Gloves should be worn during application.

  Wash hands after use.

  In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.

  The product may cause reactions in sensitive individuals. If you have known hypersensitivity for non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.

  Avoid accidental self-injection.
- Additional precautions:

  None.
- Use during pregnancy and lactation:

  The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.

  Safety studies have not been conducted in pregnant animals.
- Interactions with other medicinal products and other forms of interactions:

  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:
  Symptomatic therapy as necessary. Maintain adequate hydration.
- Incompatibilities:
  None Known.

11. Storage instructions:

- Prevent 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 and thereby prevent 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 the month.
- Storage conditions:
  Store at a temperature below 25°C and protect from light.
  Keep the container in the outer carton.
  Store upright only.
  After opening of the package, the product should be used up within 28 days.
  Remains of the product should be discarded after 28 days.

12. Special precautions for the disposal of unused veterinary medicinal products 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 of as toxic waste. Do not dispose of sewage.

13. Further information:

- In addition to the active ingredients the medicine also contains:
  Glycerol Formal, Polyethylene Glycol 200, Magnesium Oxide Light, Sodium Formaldehyde Sulphoxylate, Ethanolamine, Water for Injection.
- Pharmaceutical form:
  A clear dark amber solution.
- Packaging size:
  Supplied in 50 ml or 100 ml glass vials, sealed with bromobutyl rubber bungs and aluminium caps.
  Not all pack sizes may be marketed.

- **Registration holder and address:**
  Comex Ltd., 1 Nablus Road, POB 19943, Jerusalem, 97200

- **Manufacturer and address**:
  Norbrook Laboratories Limited, Station Works, Newry, Co. Down, BT35 6JP, Northern Ireland, UK

Revised in May 2022 according to MoH's guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 082-09-92270-00