SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hexasol Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Oxytetracycline (as dihydrate)	30% w/v [300 mg/ml]
Flunixin (as flunixin meglumine)	2.0% w/v [20 mg/ml]

Excipients

Sodium Formaldehyde Sulphoxylate	0.4 % w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A clear dark amber solution.

4. CLINICAL PARTICULARS

4.1 Target species:

Cattle.

4.2 Indications for use, specifying the target species:

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.

4.3 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.

4.4 Special Warnings for Each Target Species:

None known.

4.5 Special Precautions for Use:

Special Precautions for use 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.

4.6 Adverse reactions (frequency and seriousness):

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.

The frequency of adverse reactions is defined using the following convention:

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation 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 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.

4.8 Interactions with other medicinal products and other forms of interaction:

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 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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary):

Symptomatic therapy as necessary. Maintain adequate hydration.

4.11 Withdrawal periods:

Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

Not for use in cattle producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial, anti-inflammatory

ATCvet Code: QJ01AA56

5.1 Pharmacodynamic properties:

The tetracyclines are a family of broad-spectrum bacteriostatic antibiotics which inhibit protein synthesis in susceptible microorganisms. A wide range of organisms are known to be sensitive *in vitro* to oxytetracycline, including *Pasteurella* spp, *Arcanobacterium pyogenes, Staphylococcus aureus* and certain mycoplasmas.

After oxytetracycline diffuses through the outer bacterial cell membrane, an active carrier mediated process transports the drugs through the inner cytoplasmic membrane. Inside the cell, oxytetracycline binds irreversibly to receptors on the 30S sub-unit of the bacterial ribosome where it interferes with the binding of the aminoacyl-transfer RNA to the acceptor site on the messenger RNA ribosome complex. This effectively prevents the addition of amino acids to the elongating peptide chain, inhibiting protein synthesis.

Flunixin meglumine is a relatively potent non-narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties.

Flunixin meglumine acts as a reversible inhibitor of cyclo-oxygenase, an important enzyme in the arachidonic acid cascade pathway which is responsible for converting arachidonic acid to cyclic endoperoxides. Consequently, synthesis of eicosanoids, important mediators of the inflammatory process involved in central pyresis, pain perception and tissue inflammation, is inhibited. Through its effects on the arachidonic acid cascade, flunixin also inhibits the production of thromboxane, a potent platelet pro-aggregator and vasoconstrictor which is released during blood clotting. Flunixin exerts its antipyretic effect by inhibiting prostaglandin E_2 synthesis in the hypothalamus. By inhibiting the arachidonic acid cascade pathway, flunixin also produces an anti-endotoxic effect by suppressing eicosanoid formation and therefore preventing their involvement in endotoxin associated disease states.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Glycerol Formal
Polyethylene Glycol 200
Magnesium Oxide Light

Sodium Formaldehyde Sulphoxylate
Ethanolamine
Water for Injections

6.2 Incompatibilities:

None Known

6.3 Shelf-life:

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage:

Store upright only.
Keep the container in the outer carton.
Do not store above 25°C.
Following withdrawal of the first dose, the product should be used within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging:

Supplied in 50 ml and 100 ml Type I, amber glass vials, sealed with bromobutyl rubber bungs and aluminium caps.
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, if appropriate:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MANUFACTURER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. IMPORTER AND MARKETING AUTHORISATION HOLDER

Comex Ltd.
1 Nablus Road, POB 19943, Jerusalem, 97200

9. MARKETING AUTHORISATION NUMBER

082-09-92270-00

Revised in May 2022 according to MoH’s guidelines.