For Animal Use Only

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

HEXASOL HB Injection

COMPOSITION:

Each ml contains oxytetracycline dihydrate equivalent to oxytetracycline 300 mg/ml and flunixin meglumine equivalent to flunixin 20 mg/ml. Sodium formaldehyde sulphoxylate 0,4 % is added at the time of manufacture as an antioxidant.

PHARMACOLOGICAL CLASSIFICATION:

C.17.1.11 Antibacterial combinations

PHARMACOLOGICAL ACTION:

The tetracyclines are a family of broad-spectrum bacteriostatic antibiotics that inhibit protein synthesis in susceptible microorganisms. The tetracyclines, including oxytetracycline are active against many gram-positive and gram-negative bacteria. Mycoplasma, chlamydia, rickettsia and some protozoa are also susceptible. By binding to receptors of the bacterial ribosome, oxytetracycline inhibits protein synthesis.

The action on protein synthesis is relatively specific for bacterial cells and similar actions on mammalian cells do not occur at clinical dose rates. Oxytetracycline is therefore selectively toxic for bacterial cells.

Flunixin meglumine is a potent non-narcotic, non-steroid 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 are inhibited. Through its effects on the arachidonic acid cascade, flunixin also inhibits the product of thromboxane, a potent platelet pro-aggregator and vasoconstrictor, which is released during blood clotting. Flunixin exerts its antipyretic effect by inhibiting prostaglandin E2 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 disease states. *In vitro* antibacterial sensitivity does not necessarily imply *in vivo* activity.

INDICATIONS:

HEXASOL HB Injection is indicated for the treatment of respiratory infections, and the associated pyresis, caused by oxytetracycline-sensitive organisms, in cattle.

CONTRAINDICATIONS:

Use is contraindicated in animals suffering from cardiac, hepatic, or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding or where there is hypersensitivity to the product.
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Safety in pregnancy has not been established.

WARNINGS AND SPECIAL PRECAUTIONS:

Avoid intra-arterial injection.
Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 21 days from the last treatment.
Not for use in cattle producing milk for human consumption.
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 dose and careful clinical management.
Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity.

INTERACTIONS:

Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound medicines which can lead to toxic effects. Concurrent administration of potentially nephrotoxic medicines should be avoided.

DOSAGE AND DIRECTIONS FOR USE:

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

HEXASOL HB is indicated for intramuscular or subcutaneous administration to cattle.

The recommended dose rate is 1 ml per 10 kg body mass (equivalent to 2 mg/kg flunixin and 30 mg/kg oxytetracycline).

The period of time between the withdrawal of the first and final doses should not be unduly prolonged, and used within 28 days after broaching of the vial.

Do not administer more than 15 ml at any one injection site.

SIDE EFFECTS:

Untoward effects include gastrointestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage. Prolonged use or higher than recommended dose rates may cause gastro-intestinal ulceration and may lead to a life-threatening plasma protein enteropathy. Nephrotoxicity in the form of papillary necrosis, bone-marrow suppression resulting in blood dyscrasias and impaired hepatic function may occur.

Ataxia, rapid breathing, muscle weakness and Central Nervous System effects (hysteria) may occur after intra-arterial administration.

Long-acting tetracycline solutions may cause tissue reactions.

Intra-muscular injections may cause temporary discomfort that will abate after one or two minutes.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage is associated with gastrointestinal toxicity.

When overdosage has occurred withdraw the medication immediately. Treatment is symptomatic and supportive.

IDENTIFICATION:

A clear, dark amber solution free from visible particles.

PRESENTATION:

HEXASOL HB is supplied in 50 ml, 100 ml, 250 ml and 500 ml amber glass vials for multiple dose use.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light. Keep out of reach of children, uninformed persons and animals.

After broaching the first time the solution will be stable for 28 days.

REGISTRATION NUMBER

99/21.1/9

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Biotech Laboratories (Pty) Ltd
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