APPROVED PACKAGE INSERT FOR BIVATOP® 200 LA

FOR ANIMAL USE ONLY

BIVATOP® 200 LA

Reg. no.: G4115 (Act 36/1947)

Namibia: V13/17.1.2/1224 (Act 13/2003)

A long-acting, broad spectrum, injectable antibiotic for the treatment and control of disease conditions associated with oxytetracycline-sensitive organisms in cattle and pigs

Dosage form:

Injectable solution

Storage Instructions:

Store at or below 25 °C. Exposure to colder temperatures than the recommended storage conditions may cause cloudiness of the injectable solution. Gently warm the bottle between your hands to restore the clarity of the solution before use.

Protect from light. Do not freeze.

Some darkening of the solution may occur without affecting the potency.

Keep out of reach of children, uninformed persons and animals.

Composition:

Each ml of injectable solution contains 200 mg oxytetracyline dihydrate.

Indications:

BIVATOP® 200 LA is indicated for the treatment and control of disease conditions associated with oxytetracycline-susceptible organisms in cattle and pigs as follows:

A large number of Gram-positive and Gram-negative bacteria, certain mycoplasma species, rickettsiae, protozoa, and the psittacosis-lympho-granuloma group (*Chlamydophila*).

BIVATOP® 200 LA is recommended wherever extended antibiotic therapy or prophylaxis is indicated, or where because of various animal husbandry conditions, frequent animal handling and repeat dosing is impractical.

Cattle:

For the treatment of anaplasmosis (gallsickness), heartwater, pneumonia, leptospirosis, necro-bacillosis, mastitis, blackleg, bacterial enteritis (scours), actinobacillosis (wooden tongue), navel/ joint-ill and wound infections.

Aids in the control or prevention of bacterial respiratory infections associated with transport or shipping and post-operative and post-parturient infections.

Pigs:

For the treatment of pneumonia, leptospirosis, erysipelas (diamond skin disease), mastitis, bacterial enteritis (scours, colibacillosis), navel/ joint-ill, and wound infections. It also aids in the control or prevention of bacterial respiratory infections associated with transport or shipping, MMA (metritis-mastitis-agalactia) syndrome in sows, scours in suckling piglets and post-operative and post-parturient infections.

Warnings:

- **Withdrawal period: The meat of treated animals may not be used for human consumption within 28 days, and the milk within 4 days, after the last treatment.**
- Rapid intravenous administration may result in the collapse of the animal. **BIVATOP® 200 LA** should therefore be administered slowly intravenously over a time period of at least 5 minutes.
- Do not administer **BIVATOP® 200 LA** to piglets on the same day that they are injected with parenteral iron.
- Shortly after administration treated animals may have a transient haemoglobinuria resulting in darkened urine.
- Temporary localised swelling may be observed at the injection site post treatment.

- Muscle discolouration may necessitate trimming of the injection site and surrounding areas during the post-slaughter meat processing and meat inspection phase in cattle.
- Keep out of reach of children, uninformed persons and animals.
- Although this remedy has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

Precautions:

- Consult your veterinarian for an accurate diagnosis.
- Care should be taken avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the medical doctor.
- Bacteriostatic antibiotics may interfere with the bactericidal mechanism of action of penicillin therefore avoid administering **BIVATOP® 200 LA** in conjunction with any penicillin.
- In the event of any adverse reactions observed during or after treatment, discontinue treatment with **BIVATOP® 200 LA** immediately and consult your veterinarian to determine the proper treatment required for such reactions.

Dosage and directions for use:

Use only as directed. Handle aseptically.

BIVATOP® 200 LA is to be administered by deep intramuscular (the preferred injection site for slaughter animals is the neck) or subcutaneous injection to cattle and pigs and by **intravenous** injection to cattle **only**.

A single intramuscular or subcutaneous injection of **1 ml BIVATOP® 200 LA/ 10 kg** body mass equivalent to **20 mg oxytetracycline/ kg** body mass is indicated to provide sustained antibiotic action over 3 to 5 days for the prevention or treatment of the susceptible disease condition of cattle and pigs where re-treatment is impractical due to various animal husbandry reasons. However in more chronic disease conditions a second treatment 48 to 72 hours following the first treatment may be administered.

Cattle:

1 ml per 10 kg body mass by deep intramuscular, subcutaneous or intravenous injection. Intravenous injection of **BIVATOP® 200 LA** does not achieve any long-acting effect. If administered intravenously, **BIVATOP® 200 LA** must be given slowly over a time period of at least 5 minutes to prevent potential collapse of the animal.

Do not administer more than 10 ml at any one subcutaneous or intramuscular injection site and not more than 1 to 2 ml per injection site in small calves to minimise local tissue reaction.

Pigs:

Piglets less than 2 kg body mass: 0,5 ml **BIVATOP® 200 LA** subcutaneously behind the ear.

Piglets 2 to 10 kg body mass: 1 ml subcutaneously behind the ear.

Pigs in excess of 10 kg: 1 ml/ 10 kg body mass by deep intramuscular injection. Administer a maximum of 5 ml per injection site.

Presentation:

Cardboard box containing either 1 or 12 multidose bottles of 100 ml or 250 ml of ready to use injectable solution.

Cardboard box containing either 1 or 6 multidose bottles of 500 ml of ready to use injectable solution.

Registration holder:

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