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For Animal Use Only

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

ULTRAJECT Injection

COMPOSITION:

Each ml contains 300 mg procaine benzylpenicillin in a stable injectable suspension.

Butylhydroxyanisol 0,07 % *m/v* and butylhydroxytoluene 0,07 % *m/v* are included as antioxidants.

PHARMACOLOGICAL CLASSIFICATION:

C 17.1.1.1 Penicillins

PHARMACOLOGICAL ACTION:

Procaine benzylpenicillin is a beta-lactam antibiotic and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins.

Procaine benzylpenicillin shows activity against susceptible Gram-positive bacteria such as streptococci, corynebacteria, *Erysipelothrix* spp, clostridia and staphylococci (non-penicillinase producing) but has limited activity against Gram negative bacteria with the exception of the more fastidious Gram-negative aerobes such as *Pasteurella* spp.

Beta-lactam antibiotics prevent the bacterial cell wall from forming by interfering with peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action and cause lysis of growing cells.

In vitro sensitivity does not necessarily imply *in vivo* efficacy.

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INDICATIONS:

Target Species: Cattle, Pigs and Sheep.

ULTRAJECT Injection is indicated for use in cattle, pigs and sheep in the treatment and control of a wide range of common systemic, respiratory, urinary and local infections caused by or associated with organisms sensitive to penicillin, including *Arcanobacterium pyogenes*, *Erysipelothrix rhusiopathiae*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Staphylococcus* spp. (nonpenicillinase producing) and *Streptococcus* spp.

ULTRAJECT Injection will therefore be effective in the treatment of infections caused by susceptible organisms including:

Erysipelas;

Navel/joint-ill;

Respiratory tract infections, including pneumonia and atrophic rhinitis;

Meningitis;

Septicaemia;

Toxaemia associated with mastitis, and

Urogenital tract infections.

CONTRAINDICATIONS:

ULTRAJECT Injection is contraindicated in known cases of hypersensitivity to penicillins and related compounds.

Do not inject intravenously or intrathecally.

Not to be used on small herbivores such as rabbits, guinea pigs, gerbils and hamsters.

Psittacine birds are sensitive to procaine.

WARNINGS AND SPECIAL PRECAUTIONS:

Anaphylactic shock may occur when administered to an animal known to be hypersensitive.

Adrenaline, corticosteroids and antihistamines should be used to treat anaphylaxis.

If injection is administered subcutaneously:

Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 10 days from the last treatment.

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Sheep may be slaughtered for human consumption only after 12 days from the last treatment.

Milk must not be taken for human consumption during treatment.

If injection is administered intramuscularly:

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.

Pigs may be slaughtered for human consumption only after 7 days from the last treatment.

Sheep may be slaughtered for human consumption only after 12 days from the last treatment.

Milk for human consumption must not be taken during treatment.

Milk for human consumption may only be taken from treated cows after 5 days from the last treatment.

Special precautions to be taken by the person administering the product to the animals:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are hypersensitive, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you were exposed to this product and develop hypersensitivity reactions such as skin rash, or the more serious symptoms such as swelling of the face, lips or eyes or are experiencing difficulty in breathing you should seek immediate medical attention or be taken to the nearest hospital.

DOSAGE AND DIRECTIONS FOR USE:

ULTRAJECT Injection is indicated for intramuscular administration to cattle, pigs and sheep and subcutaneous administration to non-lactating cattle. Use content within 28 days after first withdrawal.

The recommended dose rate is 20 mg procaine penicillin/kg body-mass equivalent to 1 ml per 15 kg body mass at 48 hour intervals until the required response has been achieved or until treatment is re-evaluated.

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SIDE EFFECTS:

Occasionally in suckling and fattening pigs administration of penicillin may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination. Additionally in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

Although procaine benzylpenicillin is well tolerated, occasionally a slight local reaction of a transient nature may be observed.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See side effects. Treatment is symptomatic and supportive.

IDENTIFICATION:

Oily white/off white suspension in clear glass vials.

PRESENTATION:

ULTRAJECT injection is supplied in 50 ml and 100 ml clear glass vials.

STORAGE INSTRUCTIONS:

Use content within 28 days after first withdrawal.

Store at or below 25 °C. Protect from light.

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

REGISTRATION NUMBER:

00/21.1/2

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

Biotech Laboratories (Pty) Ltd

(Reg. No. 1990/007220/07)

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15 June 2005