

**PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY**

Ultrapen LA

Procaine Penicillin Injection for Cattle and Pigs

PROCAINE PENICILLIN 300 mg/mL

PHARMACOLOGY

Benzylpenicillin (penicillin G) is a member of the β -lactam group of antibiotics, the structure of which contains the β -lactam ring and thiazolidine ring, a common feature of all penicillins.

Mode of Action:

β -lactam antibiotics prevent the bacterial cell wall from forming by interfering with the final stage of 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 but cause lysis only of growing cells. Various factors account for the difference in susceptibility between gram-positive and gram-negative bacteria which include receptor site differences, the relative amount of peptidoglycan present, the differential ability of drugs to penetrate the outer cell membrane of gram-negative bacteria and resistance to the different types of β -lactamase enzymes produced by the bacteria.

Penicillin G-Containing Preparations:

The incompatibility of penicillin G with gastric acid and its instability in acidic environments precludes its oral administration, therefore penicillin G is usually administered parenterally. Due to the relative instability of benzylpenicillin it is produced in a variety of organic salts, one of which is procaine penicillin. Delayed absorption is frequently required to maintain adequate blood serum and tissue antibiotic concentrations since excretion of the penicillins is rapid and the slowing of excretion impracticable. By suspending an "insoluble" penicillin such as procaine penicillin in oil, therapeutic blood levels may be maintained for several days following a single injection (Brander et al, 1982). Following absorption, penicillins are widely distributed throughout the body fluids and tissues, with the volume of distribution tending to reflect extracellular compartmentalisation. Significant levels of the penicillins, including penicillin G, are encountered in the liver, muscle, kidney and lungs with only low concentrations occurring in poorly perfused areas such as the cornea, cartilage and bone. In inflammatory conditions, effective levels of the penicillins are often found in abscesses in addition to pleural, peritoneal and synovial fluids. In plasma, penicillins are reversibly and loosely bound to plasma proteins, the degree of protein binding in bovine plasma reported as being 49% [Kunin, 1967 (cited in Nix, 1991)]. Intramuscular and subcutaneous sites provide for passage of drug to the bloodstream more slowly and maintain concentrations for longer periods than intravenous administration. The former routes have the added advantage of being more convenient and less hazardous than intravenous administration. As indicated above, absorption from subcutaneous or intramuscular sites can be slowed by the use of relatively insoluble salts and/or the use of formulations in water immiscible oily vehicles.

DESCRIPTION

ULTRAPEN LA Procaine Penicillin Injection for Cattle and Pigs is a long-acting formulation of procaine penicillin.

INDICATIONS

ULTRAPEN LA is for use in the treatment and control of infections caused by susceptible penicillin-sensitive organisms in cattle and pigs.

Procaine penicillin, as in ULTRAPEN LA, has broad spectrum activity against gram-positive organisms such as *Arcanobacterium pyogenes* (formerly *Corynebacterium pyogenes*), *Erysipelothrix rhusiopathiae*, *Staphylococcus* spp (non- β -lactamase producing) and *Streptococcus* spp and is also active against the more fastidious gram-negative aerobes such as *Haemophilus* spp, *Mannheimia* spp (formerly *Pasteurella* spp) and *Actinobacillus* spp. Thus ULTRAPEN LA has clinical implications in the treatment of infections in cattle and pigs caused by these susceptible organisms including:

- Erysipelas;
- navel/joint-ill;
- respiratory tract infections, including pneumonia and atrophic rhinitis;
- meningitis;
- toxaemia associated with mastitis;
- urogenital tract infections; and the control of secondary bacterial invaders in diseases primarily of viral origin.

Net contents: 50 mL and 100 mL

DIRECTIONS FOR USE
SHAKE WELL BEFORE USE

Restraints:

DO NOT USE when it is known that β -lactamase producing bacteria are involved.
For subcutaneous (CATTLE) or intramuscular (cattle and pigs) injection only. **INTRAMUSCULAR INJECTIONS SHOULD BE GIVEN INTO THE MUSCLES OF THE NECK.**

Constraints:

Contra-indicated in animals known to be allergic to penicillin. Persons who are allergic to penicillins should avoid direct contact with the product.

Side Effects:

Transient swelling may occur at the injection site when the product is given subcutaneously. Occasionally in suckling and fattening pigs administration of such product may cause transient pyrexia, vomiting, shivering, listlessness and inco-ordination in pigs. Additionally, in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

Dosage:

The recommended dose rate is 20 mg/kg (1 mL/15 kg). When given intramuscularly, the maximum volume to be injected into a single site is 10 mL.

For example:

Cattle: 40 mL for a 600 kg animal

Pigs: 4 mL for a 60 kg animal

Repeat dose after 3 to 4 days if required.

Following withdrawal of the first dose, the product should be used within 28 days and any unused portion discarded.

Any variation by the prescribing veterinarian to the approved dose, frequency, duration, route, disease or target species may result in the need to extend the approved withholding period.

WITHHOLDING PERIODS

MEAT:

Cattle – DO NOT USE less than 21 days before slaughter for human consumption.

Pigs – DO NOT USE less than 7 days before slaughter for human consumption.

MILK: Milk collected from cows within 120 hours (10 milkings) following treatment MUST NOT BE USED for human consumption or processing, or fed to bobby calves.

TRADE ADVICE:

EXPORT SLAUGHTER INTERVALS (ESIs)

Cattle - DO NOT USE less than 21 days before slaughter for export.

Pigs – DO NOT USE less than 7 days before slaughter for export.

The ESIs on this label were correct at the time of label approval. Before using this product confirm the current ESI from the distributor on 1800 665 866 or the APVMA website (<http://www.apvma.gov.au/residues/ESI.shtml>).

Dispose of empty container by wrapping with paper and putting in garbage.

Store below 25°C (Air conditioning). Protect from light

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References:

Brander GC, Pugh DM and Bywater RJ (Editors). IN: Veterinary Applied Pharmacology & Therapeutics, Fourth Edition, 1982 Chapter 26:369-375

Nix DE, Goodwin SD, Peloquin CE, Rotella DL and Schentag JJ (1991). Antibiotic tissue penetration and its relevance: Impact of tissue penetration on infection response. *Antimicrobial Agents and Chemotherapy* 35(19):1953-1959