SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ultrapen LA 30% Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Procaine Benzylpenicillin 30%w/v [300 mg/ml]

Excipients:
Butylhydroxyanisole (E320) as an antioxidant: 0.007% w/v
Butylhydroxytoluene (E321) as an antioxidant: 0.007% w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for Injection
An oily white/off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Pigs

4.2 Indications for use, specifying the target species

Procaine penicillin G is specifically formulated to provide sustained antibacterial activity following a single administration.

Ultrapen LA is indicated for use in cattle and pigs 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 *Trueperella pyogenes*, *Erysipelothrix rhusiopathiae*, *Mannheimia haemolytica*, *Pasteurella multocida* and *Streptococcus* spp.

Ultrapen LA 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; urogenital tract infections and the control of secondary bacterial invaders in diseases primarily of viral origin.

4.3 Contraindications

Ultrapen LA is contraindicated in known cases of hypersensitivity to penicillins.

Do not inject intravenously or by the intrathecal route.

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

4.4 Special Warnings for each target species

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g., blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the product for treatment of meningitis or CNS infections due to e.g., *Streptococcus suis* or *Listeria monocytogenes* may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly and hence this product may have little effect in treating intracellular pathogens e.g., *Listeria monocytogenes*

Elevated MIC values or bi-modal distribution profiles suggesting acquired resistance have been reported for the following bacteria:
Glaesserella parasuis, *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. and *S. suis* in pigs;
Fusobacterium necrophorum causing metritis and *Mannheimia haemolytica,* as well as *Bacteroides* spp., *Staphylococcus chromogenes, Actinobacillus lignieresii* and *Trueperella pyogenes* in cattle.

Use of the veterinary medicinal product may result in a lack of clinical efficacy when treating infections caused by these bacteria.

4.5 Special precautions for use

i) Special precautions for use in animals

Shake the vial before use. This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry sterile needle and syringe.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Take care to avoid accidental injection. Wash hands after use.

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 sensitised, 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 develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

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 Ultrapen LA is well tolerated, occasionally a slight local reaction of a transient nature may be observed.

Systemic toxic effects have been observed in young piglets, which are transient but can be potentially lethal, especially at higher doses.

4.7 Use during pregnancy, lactation or lay

Ultrapen LA is safe for use during pregnancy and lactation.
In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

4.8 Interaction with other medicinal products and other forms of interaction

It is inadvisable to use other antibiotics concurrently

4.9 Amounts to be administered and administration route

Ultrapen LA is indicated for intramuscular and subcutaneous administration to non-lactating cattle and for intramuscular administration to pigs and lactating cattle.

The recommended dose rate is 20 mg procaine penicillin/kg bodyweight equivalent to 1 ml per 15 kg bodyweight. If signs persist at 72 hours repeat the dose.

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

Penicillins have a very wide safety margin.

4.11 Withdrawal period

Subcutaneous Administration
Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 13 days from the last treatment.

Intramuscular Administration
Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 23 days from the last treatment.
Pigs may be slaughtered for human consumption only after 10 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 132 hours from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ01CE09

5.1 Pharmacodynamic properties

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

Penicillin G shows excellent activity against susceptible Gram-positive bacteria such as *Streptococci, Trueperella, Erysipelothrix and Clostridia* 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 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.

Enterobacterales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas spp*. as well as beta-lactamase–producing *Staphylococcus* spp. are resistant.

5.2 Pharmacokinetic properties

After injection of Ultrapen LA, the procaine penicillin is rapidly absorbed from the site of injection with maximum penicillin levels of approximately 3.9µg/ml obtained in under 4.5 hours of subcutaneous injection in cattle, 1.3µg/ml obtained in under 4 hours of intramuscular injection in cattle and 2.1 µg/ml obtained in under 3 hours of intramuscular injection in pigs.
The penicillin elimination half-lives are approximately 16 hours for cattle and 7.5 hours for pigs following intramuscular injection and 8.5 hours for cattle following subcutaneous injection.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxyanisole
Butylated Hydroxytoluene
Aluminium Distearate
Propylene Glycol Dicaprylate/Dicaprate

6.2 Incompatibilities

None Known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
Glass containers: 2 years
Plastic containers: 3 years
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25ºC. Protect from light.

Following the withdrawal of the first dose, the product should be used within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

50 ml and 100 ml type II clear glass vials, with nitryl bungs and aluminium caps.
50 ml, 100 ml, 250 ml and 500 ml clear polyethylene terephthalate (PET) vials, with nitryl bungs and aluminium caps.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4133

9. DATE OF FIRST AUTHORISATION

21 January 1997

10. DATE OF REVISION OF THE TEXT

June 2024

Approved 18 June 2024
Gavin Hall