Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ultrapen LA 300 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:		
Procaine Benzylpenicillin	300	mg
Excipients:		
Butylhydroxyanisole (E320)	0.1	mg
Butylhydroxytoluene (E321)	0.1	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection. A white to off-white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and pigs.

4.2 Indications for use, specifying the target species

Ultrapen LA 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 *Corynebacterium pyogenes*, *Erysipelothrix rhusiopathiae*, *Pasteurella haemolytica*, *Pasteurella multocida*, *Staphylococcus* spp. (non-penicillinase producing) 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; toxaemia associated with mastitis; urogenital tract infections and the control of secondary bacterial invaders in diseases primarily of viral origin.

4.3 Contraindications

Do not administer by the intravenous route.

Do not use on very small herbivores such as guinea pigs, gerbils and hamsters.

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special Precautions to be taken by the Person Administering the Medicinal Product to 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 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.

4.7 Use during pregnancy, lactation or lay

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 interactions

None known.

4.9 Amounts to be administered and administration route

Shake the vial before use.

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 necessary, the dose may be repeated after 72 hours. The stopper should not be punctured more than 10 times. A draw off needle should be used to avoid excessive puncturing of the stopper.

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

None known.

4.11 Withdrawal period(s)

Subcutaneous Administration

Animals intended for human consumption may not be slaughtered during treatment.
Cattle 10 days: Cattle may be slaughtered for human consumption only after 10 days from the last treatment.

Intramuscular Administration

Animals must not be slaughtered for human consumption during treatment.
Cattle: 21 days. Cattle may be slaughtered for human consumption only after 21 days from the last treatment.
Pigs: 7 days. Pigs may be slaughtered for human consumption only after 7 days from the last treatment.

Milk for human consumption must not be taken during treatment.
Milk: 5 days. Milk intended for human consumption may be taken after 5 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, procaine penicillin. ATC Vet Code: QJ01CE09.

5.1 Pharmacodynamic properties

Penicillin G is a beta-lactam anitbiotic 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, Corynebacterium, Erysipelothrix, 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 anitbiotics 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate
Butylhydroxyanisole (E320)
Butylhydroxytoluene (E321)
Propylene glycol dicaprylocaprate

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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 25°C.
Keep the vials in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

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

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/045/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 December 1997
Date of last renewal: 11 December 2007

10 DATE OF REVISION OF THE TEXT

January 2019