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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E320)	0.1 mg
Butylhydroxytoluene (E321)	0.1 mg
Aluminium Distearate	
Propylene Glycol Dicaprylate / Dicaprate	

A white to off white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is specifically formulated to provide sustained antibacterial activity following a single administration.

The veterinary medicinal product is indicated for use in cattle and pigs in the treatment 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, Staphylococcus* spp (non-penicillinase producing) and *Streptococcus* spp.

The veterinary medicinal product 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 secondary bacterial invaders in diseases primarily of viral origin.

3.3 Contraindications

Do not administer by the intravenous route. Do not use on very small herbivores such as guinea pigs, gerbils or hamsters. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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:
- *Staphylococcus* spp. causing MMA/PPDS, *Streptococcus* spp. in pigs;
- *Mannheimia haemolytica* 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary 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 package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Cattle, Pigs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[1]

[1]Localised and transient.

Target species: Pigs

Very rare	Vomiting[1]

(<1 animal / 10,000 animals treated, including isolated reports):	Shivering, Incoordination[1] Pyrexia, Listless[1]Vaginal discharge[2]

[1]In suckling and fattening pigs.
[2]In pregnant sows and gilts, a vulval discharge which could be associated with abortion has been reported.

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.
In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Shake the vial before use.

The veterinary medicinal product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Subcutaneous Administration:

Cattle:
Meat and offal: 10 days.

Animals intended for human consumption may not be slaughtered during treatment.

Intramuscular Administration:

Cattle:
Meat and offal: 21 days.
Milk: 5 days.

Pigs:
Meat and offal: 7 days.

Animals must not be slaughtered for human consumption during treatment.
Milk for human consumption must not be taken during treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CE09

4.2 Pharmacodynamics

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, 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 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. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.
Keep the vials in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

50 ml and 100 ml Grade II clear glass vials, complete with nitryl bungs and aluminium caps.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/045/001

8. DATE OF FIRST AUTHORISATION

12/12/1997

9. DATE OF THE LAST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

15/07/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).