SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocillin LA Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance(s)	% w/v
Benzathine Penicillin	11.25
Procaine Penicillin	15.00
Excipients	
Methyl Parahydroxybenzoate	0.200
Propyl Parahydroxybenzoate	0.020

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for Injection
An off-white Suspension

4. CLINICAL PARTICULARS

4.1 Target species

Horses
Dogs
Cats

4.2 Indications for use, specifying the target species

For the treatment of systemic infections caused by or associated with organisms sensitive to penicillin.

4.3 Contraindications

Do not inject intravenously.
Do not use in known cases of hypersensitivity to penicillin.
Not to be used on very small herbivores such as guinea pigs, gerbils and hamsters.

4.4 Special Warnings for each target species

None known

4.5 Special precautions for use

i. Special precautions for use in animals

Shake the container before use.
Care should be taken not to overdose.
Not effective against beta-lactamase producing organisms.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

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

Care should be taken to avoid accidental self-injection .
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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Norocillin LA can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer by deep intramuscular injection only. For a single administration only.
Large animals: 6 mg/kg bodyweight procaine penicillin with 4.5 mg/kg bodyweight benzathine penicillin equivalent to 1 ml per 25 kg bodyweight
Small animals: 15 mg/kg procaine penicillin with 11.25 mg/kg benzathine penicillin equivalent to 1 ml per 10kg bodyweight.

Bodyweight should be determined as accurately as possible prior to calculating the correct dosage.

Horses:	500kg-20ml
Dogs:	10kg-1ml
Cats:	5kg-0.5ml

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

Penicillins have a wide margin of safety.

4.11 Withdrawal period

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use

ATC Vet Code: QJ01CE3

5.1 Pharmacodynamic properties

Norocillin LA is administered by deep intramuscular injection to create a depot from which benzylpenicillin is slowly liberated. Antimicrobial activity is achieved by interference in the final stage of bacterial cell wall synthesis by binding to the PBP's (penicillin binding proteins).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Polysorbate 80
Povidone K12

Disodium Edetate Dihydrate
Potassium Acid Phosphate
Sodium Citrate Dihydrate
Carmellose Sodium
Propylene Glycol
Antifoam M30
Water for Injections

6.2 Incompatibilities

None known

6.3 Shelf life

The shelf life of the veterinary medicinal product as packaged for sale: 1 year.
The shelf life after opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C
Protect from light.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused suspension.

6.5 Nature and composition of immediate packaging

50ml and 100ml clear, colourless, Type II glass vials with bromobutyl rubber bung with aluminium overseal.

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 requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm: 02000/4057

9. DATE OF FIRST AUTHORISATION

4th April 1985

10. DATE OF REVISION OF THE TEXT

April 2014

04 April 2014