Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norocaine Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains
Active Substances

Lidocaine (Lignocaine) Hydrochloride	20.00	mg
Epinephrine (Adrenaline as Adrenaline Acid Tartrate)	0.0125	mg

Excipients

Chlorocresol (preservative)	1.00	mg
Sodium metabisulphite (as an antioxidant)	1.00	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear colourless solution

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

For infiltration anaesthesia (local or field block) and regional anaesthesia.

4.3 Contraindications

Do not administer by intravenous injection.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The product is available in 100 ml and 500 ml pack sizes. The 500 ml pack size should only be used in appropriate situations. It should not be used for the administration of multiple small dose volumes over an extended period of time.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Local infiltration of the product may delay wound healing.

4.7 Use during pregnancy, lactation or lay

Norocaine Injection can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None.

4.9 Amounts to be administered and administration route

For subcutaneous and intramuscular injection only.

Local infiltration and field block anaesthesia: Up to 100 - 200 ml per surgical site

Regional anaesthesia: Approx 7 ml per site.

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

In mild cases of overdose, animals may become anxious and restless. The symptoms are transient and will pass off with little or no treatment being necessary.

In severe cases of overdose convulsions may occur and respiratory and circulatory failure may follow. Such symptoms may also follow inadvertent intravenous administration. Overdosage may be treated by administering respiratory stimulants and keeping animals warm

4.11 Withdrawal period(s)

Meat and offal: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nervous system, anesthetics, local, amides; lidocaine, combinations
ATC vet code: QN01BB52

Lidocaine is an aminoacyl amide and an effective local analgesic. When administered locally it prevents conduction of the nerve impulse by disrupting the migration of sodium ions across the nerve membrane. Adrenaline acts a vasoconstrictor when administered locally and therefore delays the absorption of Lidocaine from the site of action, and prolongs the analgesic effect.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Sodium Metabisulphite
Chlorocresol
Water for Injection

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

The expiry date for Norocaine Injection should not exceed 2 years from the date of manufacture. Following withdrawal of the first dose, use the product within 28 days.

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light

6.5 Nature and composition of immediate packaging

100 ml and 500 ml amber type II glass vials, closed with brombutyl bungs, and aluminium overseals. Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/036/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1990
Date of last renewal: 30 September 2010

10 DATE OF REVISION OF THE TEXT

January 2019