SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Locaine 2%w/v Solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Lidocaine Hydrochloride	2.0 %w/v
Adrenaline Acid Tartrate	0.00227 %w/v

Excipients:

Chlorocresol (as antimicrobial preservative)	0.1%w/v
Sodium Metabisulphite (as antioxidants)	0.1%w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection
A clear almost colourless to pale yellow sterile aqueous 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 including paravertebral nerve blocks.

4.3 Contraindications

Do not administer by intravascular injection.

4.4 Special Warnings for each target species

Care should be taken in the administration of repeat doses in cases where the desired degree of anaesthesia has not been attained (see also 4.9).

4.5 Special precautions for use

(i) Special precautions for use in animals

Not applicable.

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

If accidental self-injection or ingestion occurs, seek medical advice immediately.
In case of eye contamination or excessive skin contact, irrigate/wash immediately with plenty of clean water. Seek medical attention if irritation persists.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Not applicable.

4.7 Use during pregnancy, lactation or lay

Locaine 2% can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For subcutaneous and intramuscular injection only.

1. Local infiltration and field block anaesthesia.
   The recommended doses are:
   Horses: Up to 100-200 ml per surgical site.

   In cases of repeated administration, the total volume administered should not exceed 0.5 ml/kg bodyweight.

2. Regional anaesthesia.

(i) Paravertebral 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. Overdosage may be treated by administering respiratory stimulants and keeping animals warm.

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: Anesthetics

ATC Vet Code: QN01BB52

5.1 Pharmacodynamic properties

Lignocaine 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 Lignocaine from the site of action, and prolongs the analgesic effect.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulphite,
Chlorocresol,
Sodium Chloride
Hydrochloride Acid, Concentrated or Sodium Hydroxide solution (for pH adjustment)
Water for injections.

6.2 Incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Do not store above 25ºC.
Protect from light.

6.5 Nature and composition of immediate packaging

100 ml amber type II glass vials, closed with bromobutyl bungs, and aluminium overseals.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4228

9. DATE OF FIRST AUTHORISATION

4th June 2004

10. DATE OF REVISION OF THE TEXT

8/10/2009