ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection for Cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Procaine Hydrochloride	50 mg
Adrenaline (Epinephrine) (as Adrenaline Tartrate)	0.02 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol (as preservative)	1.0 mg/ml

Sodium Metabisulphite E223 (as antioxidant)	1.0 mg/ml
Sodium Chloride	
Chlorocresol	
Sodium Hydroxide (pH adjustment)	
Hydrochloric Acid (pH adjustment)	
Water for Injections	

A clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for use in minor surgical procedures particularly dehorning and disbudding in cattle.

3.3 Contraindications

Do not administer by intravenous, intra-articular or epidural injection.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

3.5 Special Precautions for use

Special precautions for safe use in the target species:

Care should be taken not to inject the product intravascularly.

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

Care should be taken to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Immediately wash off any splashes to the eyes or skin with copious amounts of water.

Seek medical attention if irritation occurs. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 its local representative 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.

3.8 Interaction with other medicinal products and other forms of interaction

Procaine may inhibit the action of sulfonamides and their concurrent administration should be avoided.

3.9 Administration routes and dosage.

Subcutaneous use.

The veterinary medicinal product should be administered by subcutaneous injection as follows:

Cattle: 2-5 ml.

Avoid excessive broaching.

Do not exceed the recommended dose.

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

The product is well tolerated at doses up to 3 times the recommended dose for cattle.

Local anaesthetics used in excess can cause systemic toxicity characterised by CNS effects. If systemic toxicity occurs, as a result of inadvertent intra-vascular injection, the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.

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.

3.12 Withdrawal periods

Meat and offal: Zero days.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code:
QN01BA52

4.2 Pharmacodynamics

Procaine (p-aminobenzoyl-diethyl aminoethanol) is an amino ester. Procaine, a local anaesthetic shares with other chemical families the ability to act as a membrane stabiliser, by interfering with the ability of excitable cells to generate or transmit impulses. Procaine blocks conduction by decreasing or preventing the large transient increase in the permeability of excitable membranes to Na+ that is produced by a slight depolarisation. The action of local anaesthetics is due to their direct interaction with voltage sensitive Na+ channels.

Adrenaline is composed of two major constituents, the aromatic portion of the molecule consists of 1,2dihydroxybenzene (catechol), the aliphatic portion consists of ethanol-amine.

The duration of the action of local anaesthetics is proportional to the time which they are in actual contact with nervous tissue. Consequently procedures which localise the drug at the nerve greatly prolong the period of anaesthesia. It has been demonstrated that the addition of epinephrine to local anaesthetic solutions greatly prolongs and intensifies their action. Epinephrine performs a dual service. By decreasing the rate of absorption it not only localises the anaesthetic agent at the desired site but also allows the rate at which the anaesthetic is destroyed in the body to keep pace with the rate at which it enters the circulation. This greatly reduces systemic toxicity.

4.3 Pharmacokinetics

Procaine Hydrochloride is a local anaesthetic. The in-vitro half-life of in plasma is less than 1 minute. It is only slightly bound to plasma protein (5.8%) and has a duration of anaesthetic effect of about 50 minutes in man. Adrenaline is added to local anaesthetics such as Procaine Hydrochloride to slow diffusion and limit absorption as it constricts arterioles and capillaries, so prolonging the duration of the effect and lessening the danger of toxicity.

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: 18 months.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C.

Protect from light.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in one 100 ml amber type I glass vials with bromobutyl bungs and aluminium caps in a cardboard box.

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)

VPA 22664/087/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 17 July 2009

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

DD/MM/YYYY

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

GLASS VIAL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Procaine Hydrochloride	50 mg
Adrenaline (Epinephrine) (as Adrenaline Tartrate)	0.02 mg

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use.

5. WITHDRAWAL PERIODS

Meat and offal: Zero days.
Milk: Zero hours.

6. EXPIRY DATE

Exp: {mm/yyyy}
Once broached, use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS.

Do not store above 25°C.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

(EU)
Norbrook Laboratories (Ireland) Limited

9. BATCH NUMBER

Lot {number}

CARTON TEXT

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:

Procaine Hydrochloride	50 mg
Adrenaline (Epinephrine) (as Adrenaline Tartrate)	0.02 mg

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use as follows:

Cattle: 2-5 ml.
Avoid excessive broaching.
Do not exceed the recommended dose.

7. WITHDRAWAL PERIOD

Meat and offal: Zero days.
Milk: Zero hours.

8. EXPIRY DATE

Exp: {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep the container in the outer carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

14. MARKETING AUTHORISATION NUMBERS

VPA 22664/087/001

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Adrenacaine Solution for Injection for Cattle

2. Composition

Each ml contains:

Active substance:

Procaine Hydrochloride	50 mg
Adrenaline (Epinephrine) (as Adrenaline Tartrate)	0.02 mg
Excipients:	
Chlorocresol (as preservative)	1.0 mg/ml
Sodium Metabisulphite E223 (as antioxidant)	1.0 mg/ml

A clear colourless solution.

3. Target Species

Cattle.

4. Indications for use

The veterinary medicinal product is indicated for use in minor surgical procedures, particularly dehorning and disbudding in cattle.

5. Contraindications

Do not administer by intravenous, intra-articular or epidural injection. Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special Warnings

Special precautions for safe use in the target species:
Care should be taken not to inject the product intravascularly.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Immediately wash off any splashes to the eyes or skin with copious amounts of water.
Seek medical attention if irritation occurs.
Wash hands after use.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Procaine may inhibit the action of sulphonamides and their concurrent administration should be avoided.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Overdose:
The product is well tolerated at doses up to 3 times the recommended dose for cattle.
Local anaesthetics used in excess can cause systemic toxicity characterised by CNS effects.
If systemic toxicity occurs, as a result of inadvertent intra-vascular injection, the

administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.

Major incompatibilities:
None known.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>.

8. Dosage for each species, routes and method of administration

Subcutaneous use.

Cattle: 2 to 5 ml.

9. Advice on correct administration

Avoid excessive broaching of the closure.
Do not exceed the recommended dose.

10. Withdrawal periods

Meat and offal: Zero days.
Milk: Zero hours.

11. Special storage precautions

Do not store above 25°C.

Protect from light.

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Following withdrawal of the first dose, use the product within 28 days. Write the date to discard unused solution in the space provided on the label.

Keep the container in the outer carton.

12. Special precautions for disposal

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

applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription

14. Market authorisation numbers and pack sizes

VPA 22664/087/001

15. Date on which the package leaflet was last revised.

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions: (EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

Manufacturer responsible for batch release:

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

17. Other information