Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

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

Excipients:

Chlorocresol (as preservative)	1.0 mg/ml
Sodium Metabisulphite E223 (as antioxidant)	1.0 mg/ml

For the 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

Cattle.

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

i Special precautions for use in animals

Care should be taken not to inject the product intravascularly.

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.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product can be administered at any stage of pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

The product should be administered by subcutaneous injection as follows:

Cattle: 2-5 ml

Avoid excessive broaching.

Do not exceed the recommended dose.

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

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.

4.11 Withdrawal period(s)

Meat and offal: Zero days
Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetic

ATC Vet Code: QN01BA52

5.1 Pharmacodynamic properties

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 1,2-dihydroxybenzene (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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite (E223)
Chlorocresol
Sodium Chloride
Sodium Hydroxide (pH adjustment)
Hydrochloric Acid (pH adjustment)
Water for Injections

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

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The product will be supplied in 100 ml amber type I glass vials with bromobutyl bungs and aluminium caps.

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 products 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)

VPA22664/087/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 July 2009
Date of last renewal: 17 July 2014

10 DATE OF REVISION OF THE TEXT

August 2021