Norbrook Laboratories Ltd

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Adrenacaine Solution for Injection for Cattle

Species: Cattle

Therapeutic indication:Pharmaceuticals: Neurological preparations: Local anaesthetics

Active ingredient: Adrenaline, Procaine Hydrochloride

Product: Adrenacaine Solution for Injection for Cattle

Product index: Adrenacaine Injection

Cattle - milk: Zero hours

Cattle - meat: Zero days

Incorporating:

Qualitative and quantitative composition

Active substance(s):

Procaine Hydrochloride

Adrenaline (Epinephrine) (as Adrenaline Tartrate)

Qualitative composition of excipients and other constituents	Quantitative composition if that information is es veterinary medicinal product
Chlorocresol (as preservative)	1.0 mg/ml
Sodium Metabisulphite E223 (as antioxidant)	1.0 mg/ml

Sodium Chloride

Sodium Hydroxide (pH adjustment)

Hydrochloric Acid (pH adjustment)

Water for injections

Pharmaceutical form

Solution for injection.

A clear colourless solution.

Clinical particulars

Target species

Cattle.

Indications for use, specifying the target species

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

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.

Special Warnings for each target species

None known.

Special precautions for use

Special precautions for use in animals

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 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.

Adverse reactions (frequency and seriousness)

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

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

Interaction with other medicinal products and other forms of interaction

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

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.

Symptoms 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.

Withdrawal period

Meat and offal: Zero days

Milk: Zero hours

Pharmacological particulars

Pharmacotherapeutic group: Anaesthetic

ATC Vet Code: QN01BA52

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.

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.

Pharmaceutical particulars

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Special precautions for storage

Do not store above 25°C.

Protect from light.

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.

Special precautions for the disposal of unused veterinary medicinal product 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.

Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories Limited.

Marketing Authorisation Number

Vm 02000/4243 (UK)

Significant changes

Date of the first authorisation or date of renewal

07 July 2004

Date of revision of the text

December 2024

Any other information

Nil.

Legal category

Legal category:POM-VPS

GTIN

GTIN description: Adrenacaine Injection 100ml

GTIN:5023534004011