

**LABEL TEXT**

## LABEL TEXT

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection for Cattle

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

### 3. PHARMACEUTICAL FORM

Solution for injection

### 4. PACKAGE SIZE

100 ml

### 5. TARGET SPECIES

Cattle

### 6. INDICATIONS

### 7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

### 8. WITHDRAWAL PERIOD

Meat and offal: zero days  
Milk: zero hours

## 9. SPECIAL WARNINGS

Read the package leaflet before use for full instructions and user warnings.

## 10. EXPIRY DATE

DOM: XX/XXXX  
EXP: XX/XXXX

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.

**Date of first broaching:**  
**Date to discard:**

## 11. SPECIAL STORAGE CONDITIONS

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

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

**FOR ANIMAL TREATMENT ONLY**

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN**

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

**Marketing Authorisation Holder:**  
**(EU)**

Norbrook Laboratories (Ireland) Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland

**(UK)**

Norbrook Laboratories Limited,  
Station Works,  
Camlough Road,  
Newry,  
County Down,  
Northern Ireland  
BT35 6JP

ManA 2000

**Distributed by:**

Norbrook Laboratories Limited  
Carnbane Industrial Estate  
Newry  
BT35 6QQ  
Co. Down  
Northern Ireland

**16. MARKETING AUTHORISATION NUMBER**

VM: 02000/4243

**17. MANUFACTURER'S BATCH NUMBER**

B.N.:

**CARTON TEXT**

## DRAFT CARTON TEXT

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adrenacaine Solution for Injection for Cattle

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Procaine Hydrochloride	50mg/ml
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### 3. PHARMACEUTICAL FORM

Solution for injection

### 4. PACKAGE SIZE

100ml

### 5. TARGET SPECIES

Cattle

### 6. INDICATIONS

### 7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

### 8. WITHDRAWAL PERIOD

Meat and offal: zero days  
Milk: zero hours

**9. SPECIAL WARNINGS**

Read the package leaflet before use for full instructions and user warnings.

**10. EXPIRY DATE**

DOM: XX/XXXX

EXP: XX/XXXX

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.

**11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

**FOR ANIMAL TREATMENT ONLY**

<Supply category to be completed nationally>

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

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN**

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**Marketing Authorisation Holder:**

**(EU)**

Norbrook Laboratories (Ireland) Limited

Rossmore Industrial Estate

Monaghan

Ireland

**(UK)**

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**16. MARKETING AUTHORISATION NUMBER**

VM: 02000/4243

**17. MANUFACTURER'S BATCH NUMBER**

BN:



**INSERT TEXT**

**INSERT TEXT**

Adrenacaine Solution for Injection for Cattle

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

**Marketing Authorisation Holder:**

**(EU)**

Norbrook Laboratories (Ireland) Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland

**(UK)**

Norbrook Laboratories Limited,  
Station Works  
Camlough Road,  
Newry,  
County Down,  
Northern Ireland  
BT35 6JP

**Manufacturer responsible for batch release:**

**(EU)**

Norbrook Manufacturing Ltd.  
Rossmore Industrial Estate  
Monaghan  
Ireland

**(UK)**

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Adrenacaine Solution for Injection for Cattle

**3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS**

Procaine Hydrochloride	50mg/ml
Adrenaline (Epinephrine) (as Adrenaline Tartrate)	0.02mg/ml
Chlorocresol (as preservative)	1.0mg/ml

Sodium Metabisulphite E223 (as antioxidant)

1.0mg/ml

A clear colourless solution

#### **4. INDICATIONS**

Local Anaesthetic Injection

For minor surgical procedures, including 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. ADVERSE REACTIONS**

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

#### **7. TARGET SPECIES**

Cattle

#### **8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION**

By subcutaneous injection.  
Cattle: 2 to 5 ml

#### **9. ADVICE ON CORRECT ADMINISTRATION**

Avoid excessive broaching of the closure.

Do not exceed the recommended dose.

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

## 10. WITHDRAWAL PERIOD

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 WARNINGS

### **Special precautions for use in animals**

Care should be taken not to inject the product intravascularly.'

### **Use during pregnancy, lactation or lay**

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

### **Interaction with other medicinal products**

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 (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 intravascular injection, the administration of oxygen to treat cardio-respiratory depression and diazepam to control convulsions should be considered.

**User Warnings:**

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.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

October 2022

**15. OTHER INFORMATION**

ManA 2000

**FOR ANIMAL TREATMENT ONLY**

UK Only

POM-VPS

To be supplied only on veterinary prescription.

Vm: 02000/4243

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

**Distributed by:**

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Carnbane Industrial Estate  
Newry  
BT35 6QQ  
Co. Down  
Northern Ireland

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards to the right.

Approved 28 October 2022