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
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

100ml

5. TARGET SPECIES

Cattle

6. INDICATIONS

7. METHOD AND ROUTEOF 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)
Norbrook Laboratories Limited,
Station Works,
Camlough Road,
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Newry
BT35 6QQ
Co. Down
Northern Ireland

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 intra-vascular 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.

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Carnbane Industrial Estate
Newry
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Co. Down
Northern Ireland

Approved 28 October 2022