PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Locaine 2% w/v Solution for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Injectable solution containing:

Lidocaine hydrochloride Ph.Eur.	2%w/v
Adrenaline acid tartrate	0. 00227 %w/v
Preservative: Chlorocresol	0.1%w/v
Sodium metabisulphite,	0.1%w/v

3. PHARMACEUTICAL FORM

A colourless to pale yellow solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

Local anaesthetic for parenteral administration to horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular and subcutaneous injection only.

For further information on dosage see package leaflet.

8. WITHDRAWAL PERIOD

Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid accidental intravascular injection

USER WARNING: If accidental self-injection or ingestion occurs, seek medical advice immediately. See package leaflet for full information

10. EXPIRY DATE

Exp: dd/mm/yy

Once broached use by: ___/___/___

11. SPECIAL STORAGE CONDITIONS

Following withdrawal of the first dose, use the product within 28 days. Discard any unused material.

Do not store above 25ºC.

Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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 reach and sight of children.

POM-VPS To be supplied only on veterinary prescription.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4228

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M

Distributed by:
Animalcare Ltd
10 Great North Way
York
YO26 6RB

PACKAGE LEAFLET FOR: Locaine 2% w/v Solution for Injection

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

Norbrook Laboratories Limited
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Locaine 2% w/v Solution for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A bright almost colourless solution containing:

Lidocaine hydrochloride		2%w/v
Adrenaline acid tartrate		0.00227%w/v
Antimicrobial preservative:	Chlorocresol	0.1% w/v
	Sodium metabisulphite,	0.1%w/v

4. INDICATION(S)

Local anaesthetic for parenteral administration to horses. It may be used for infiltration anaesthesia (local or field block) and regional anaesthesia including paravertebral nerve blocks.

5. CONTRAINDICATIONS

Avoid accidental intravascular injection.

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

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular and subcutaneous injection only.

1. Local infiltration and field block anaesthesia:

The recommended dose is;

Horses: up to 100-200 ml per surgical site

In cases of repeated administration, the total volume administered should not exceed 0.5 ml/kg bodyweight.

2. Regional anaesthesia:

Paravertebral anaesthesia: Approx 7 ml per site

9. ADVICE ON CORRECT ADMINISTRATION

Care should be taken in the administration of repeat doses in cases where the desired degree of anaesthesia has not been attained.

10. WITHDRAWAL PERIOD(S)

Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Protect from light.

Do not store above 25ºC.

For animal treatment only.

Following withdrawal of the first dose, use the product within 28 days. Discard any unused material.

When the container is broached (opened) for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf life of the product is given on this package leaflet. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

USER WARNINGS: If accidental self-injection or ingestion occurs, seek medical advice immediately.

In case of eye contamination or excessive skin contact, irrigate/ wash immediately with plenty of clean water. Seek medical attention if irritation persists.

Wash hands after use.

In mild cases of overdose, animals become anxious and restless. The symptoms are transient and will pass off with little or no treatment being necessary. In severe cases of overdose convulsions may occur, and respiratory and circulatory failure may follow. Overdosage may be treated by administering respiratory stimulants and keeping animals warm.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused or empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2013

15. OTHER INFORMATION

ManA:2000
Vm 02000/4228

Package Quantities

Multidose vials of 100 ml.

POM-VPS To be supplied only by veterinary prescription.

Distributed by:
Animalcare Ltd
10 Great North Way
York
YO26 6RB

Approved: 03/08/2017