PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lignocaine and Adrenaline Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Lignocaine Hydrochloride 2.0% w/v

Adrenaline Acid Tartrate 0.00227% w/v

Preservative: Chlorocresol 0.1% w/v

Sodium Metabisulphite (as antioxidant) 0.1% w/v

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5. TARGET SPECIES

Horses

6. INDICATION(S)

Local anaesthetic for parenteral administration to horses

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous and intramuscular injection only.

Carton ONLY:

1. Local infiltration and field block anaesthesia.

The recommended doses are:
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.

(i) Paravertebral anaesthesia: Approx. 7 ml per site.

Label 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 intravascular injection.

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.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Do not store above 25º.
Protect from light. Following withdrawal of the first dose, use the product within 28 days. Discard any unused material.

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

Dispose of empty packaging and any remaining product in the household refuse.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-VPS

For animal treatment only. To be supplied only on veterinary prescription

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4135

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lignocaine and Adrenaline Solution for Injection

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

Lignocaine Hydrochloride 2.0% w/v

Adrenaline Acid Tartrate 0.00227% w/v

Preservative: Chlorocresol 0.1% w/v

Sodium Metabisulphite (as antioxidant) 0.1% w/v

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

Do not administer by intravascular injection.

6. ADVERSE REACTIONS

In mild cases of overdose, animals may 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.

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 subcutaneous and intramuscular injection only.

1. Local infiltration and field block anaesthesia.

The recommended doses are:
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.

(i) Paravertebral anaesthesia: Approx. 7 ml per site.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid accidental intravascular injection

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

[Pharmaceuticals ONLY - *The following statement should be included if there is an in-use shelf life (example: solution for injection)]*

Do not store above 25º.

Protect from light. 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, using the in-use shelf-life which is specified on this package leaflet, the

date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

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.

For Animal Treatment Only

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

Dispose of empty packaging and any remaining product in the household refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – VPS To be supplied only on veterinary prescription

Vm 02000/4135

Approved: 10/01/2018