PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbaxyl 10% w/v solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Xylazine 100 mg/ml

1.8 mg/ml Methyl Parahydroxybenzoate

0.2 mg/ml Propyl Parahydroxybenzoate

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

Virbaxyl 10% w/v solution for injection is a sedative with analgesic properties for use in horses where sedation is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for details

8. WITHDRAWAL PERIOD

Not to be used in horse intended for human consumption, see package leaflet for full warning.

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer by the intra-carotid route.

Do not administer during the last stages of pregnancy because of the risk of inducing premature parturition.

See package leaflet for further contra-indications and general precautions.

Operator Warnings

You must read the warning on the package leaflet before using this product.

General precautions:

Careful consideration should also be given before administering to animals exposed to stress conditions such as extreme heat, cold, high altitude or fatigue. Or where pulmonary disease is suspected.

Side effects of bradycardia, cardiac arrhythmia and polyuria may occur in the horse. Following intravenous administration to horses a transient rise followed by a fall in blood pressure usually occurs. Analeptics will reduce the depth, or shorten the period of sedation.

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 the National Horse Passport Legislation.

Do not exceed the recommended dosage.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25º
Keep vial in outer carton.
Following withdrawal of the first dose, use the product within 28 days.

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

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

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

POM-V

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.

To be supplied only on veterinary prescription.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac Ltd
Woolpit Business Park
Windmill Avenue, Woolpit
Bury St Edmunds
Suffolk
IP30 9UP

16. MARKETING AUTHORISATION NUMBER

Vm 11188/4001

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNIT 50ml glass vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbaxyl 10% w/v solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Xylazine 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50ml

5. TARGET SPECIES

Horses.

6. INDICATIONS

A sedative with analgesic and muscle relaxant properties for use in horses where sedation is required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for details

8. WITHDRAWAL PERIOD

Not be used for horses intended for human consumption; see package leaflet for full warning.

9. SPECIAL WARNINGS, IF NECESSARY.

Operator Warnings

You must read the warnings in the package leaflet before using this product.

Contra-indications

Do not administer by the intra-carotid route. Do not administer during the later stages of pregnancy because of the risk of inducing premature parturition. See package leaflet for further contra-indications and general precautions.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C. Following withdrawal of the first dose, use the product within 28 days.

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"

For animal treatment only.

14. THE WORDS 'KEEP OUT OF THE SIGHT AND REACH F CHILDREN'

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac Ltd
Woolpit Business Park
Windmill Avenue, Woolpit
Bury St Edmunds
Suffolk
IP30 9UP

16. MARKETING AUTHORISATION NUMBER

Vm 11188/4001 POM-V

17. MANUFACTURER'S BATCH NUMBER/EXPIRY DATE

PACKAGE LEAFLET FOR: Virbaxyl 10% w/v Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac Ltd, Woolpit Business Park, Windmill Avenue, Woolpit, Bury St Edmunds, Suffolk, IP30 9UP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbaxyl 10% w/v Solution for Injection

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

Xylazine 100 mg/ml

1.8 mg/ml Methyl Parahydroxybenzoate

0.2 mg/ml Propyl Parahydroxybenzoate

4. INDICATION(S)

Virbaxyl 10% w/v Solution for Injection is a sedative with analgesic and muscle relaxant properties for use in horses only. Virbaxyl 10% w/v Solution for Injection can be used in many cases where sedation is required, including:

1. Handling fractious animals e.g. for transportation.

2. Medical examinations e.g. X-ray examinations, removal of bandages; examination of the penis and oral cavity.

3. Premedication for minor superficial operations, and local or regional anaesthesia.

4. Elimination of defaecation when examining and treating the vagina, uterus and hindquarters.

5. CONTRAINDICATIONS

1. Do not administer by the intra-carotid route.

2. Careful consideration should be given before administering to animals exposed to stress conditions such as extreme heat, cold, high altitude or fatigue. Or where pulmonary disease is suspected.

3. Side effects such as bradycardia, cardiac arrhythmia and polyuria may occur in the horse. Following intravenous administration to horses a transient rise followed by a fall in blood pressure usually occurs. Do not exceed the recommended dosage.

4. Virbaxyl 10% w/v Solution for Injection should not be administered during the later stages of pregnancy because of the risk of inducing premature parturition. As the

safety studies of xylazine use during organogenesis has not been fully demonstrated by current methods it should be used with caution during the first month of pregnancy.

6. ADVERSE REACTIONS

See section 5 above

7. TARGET SPECIES

Horses

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

Virbaxyl 10% w/v Solution for Injection is given by slow intravenous injection. Dosage depends on the degree of sedation required and the response of the animal, and is 0.5 – 1 ml/100 kg (0.5 - 1 mg/ kg bodyweight). Nervous or excitable horses may require higher doses. Older horses and those having undergone severe physical exertion before treatment should receive the lowest dose rate. The horse does not usually become recumbent with Virbaxyl 10% w/v Solution for Injection and light to deep sedation with variable degree of analgesia is obtained. Effects are usually seen within 5 minutes and persist for approximately 20 minutes. The product may be employed as a premedication to barbiturate anaesthesia or in combination with regional or local anaesthesia.

9. ADVICE ON CORRECT ADMINISTRATION

See section 8 above

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

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. Do not store above 25ºC.. Following withdrawal of the first dose, use the product within 28 days. Keep vial in outer carton.

12. SPECIAL WARNING(S)

Operator warnings:
Horses sedated with xylazine usually remain standing and may still kick with accuracy.

Xylazine is an alpha adrenoceptor agonist acting primarily on alpha-2 receptors.
Precaution should be taken to avoid accidental injection/self-injection.
In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Avoid skin, eye or mucosal contact
Immediately after exposure, wash the exposed skin with large amounts of fresh water.
Remove contaminated clothes that are in direct contact with the skin.
In the case of accidental contact of the product with the eyes, rinse with large amounts of fresh water. If symptoms occur, seek the advice of a doctor.
If pregnant women handle the product, special precaution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to Doctors:
Xylazine is an alpha2-adrenoceptor agonist. Symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2017

15. OTHER INFORMATION

For Animal Treatment Only. Keep out of the reach and sight of children.
POM-V
Vm 11188/4001

Approved: 21 December 2017