

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

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

Vitesel Emulsion for Injection

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Alpha-Tocopheryl Acetate	68 mg/ml
Selenium (as Potassium Selenate)	1.5 mg/ml
Benzyl alcohol as antimicrobial preservative	20 mg/ml

**3. PHARMACEUTICAL FORM**

Emulsion for Injection

**4. PACKAGE SIZE**

50 ml

**5. TARGET SPECIES**

Piglets, lambs, calves and ewes

**6. INDICATION(S)**

Vitesel Injection is indicated for the prevention and treatment of Vitamin E- Selenium deficiency syndrome in piglets, lambs and calves, including various manifestations of nutritional muscular dystrophy (White Muscle Disease). Administration of Vitesel to the pregnant ewe may assist in the prevention of the deficiency syndrome of new born lambs under similar conditions.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Administer by subcutaneous or intramuscular injection to lambs and by subcutaneous injection only to ewes and by intramuscular injection only to calves and piglets.

Normal aseptic precautions should be observed. Shake well before use

**SPECIES**

**DOSAGE**

Ewes: (For protection of lambs against deficiency). 2 ml per 45 kg (100 lb) after third month of pregnancy.

New Born Lambs: 0.5 ml. Repeat after 2-4 weeks if required.

Older Lambs: 0.5 - 1.0 ml. Repeat after 2 - 4 weeks if required.

Calves: 1 - 2 ml per 45 kg (100 lb) bodyweight. Repeat after 2 - 4 weeks if required.

Piglets: 1ml per 25kg (55lb) bodyweight. Repeat after 2-4 weeks if required.

## 8. WITHDRAWAL PERIOD

Piglets, Lambs, Calves: Meat – Zero days.

Ewes : Meat – 28 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Care should be taken to avoid accidental self-injection.

Hypersensitivity reactions, particularly in cattle, have occasionally been reported following use of this product. In such an event, symptomatic treatment should be undertaken as appropriate.

The product should not be administered to ewes producing milk for human consumption

Injection site reactions may occur in some animals. These are usually of a transient nature and diminish after a few days

## 10. EXPIRY DATE

D.O. M.:

Exp.:

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

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

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light.

Keep container in outer carton.

**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** *[Distribution category]*

**For animal treatment only.**

POM-V

To be supplied only on veterinary prescription

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

**Keep out of the reach and sight of children.**

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

**Manufacturer:**

Norbrook Laboratories Limited

Newry

Co. Down

Northern Ireland

**Distributed by:**

1 Saxon Way East

Oakley Hay Industrial Estate

Corby

Northamptonshire

NN18 9EX

United Kingdom

**16. MARKETING AUTHORISATION NUMBER(S)**

ManA 2000

Vm 02000/4115

**17. MANUFACTURER'S BATCH NUMBER**

B.N.:

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vitesel Emulsion for Injection

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Alpha-Tocopheryl Acetate	68 mg/ml
Selenium (as Potassium Selenate)	1.5 mg/ml
Benzyl alcohol as antimicrobial preservative	20 mg/ml

### **3. PHARMACEUTICAL FORM**

Emulsion for Injection

### **4. PACKAGE SIZE**

50 ml.

### **5. TARGET SPECIES**

Piglets, lambs, calves and ewes

### **6. INDICATION(S)**

Vitesel emulsion for injection is indicated for the prevention and treatment of Vitamin E-Selenium deficiency in piglets, lambs, calves and ewes.

### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Administer by subcutaneous or intramuscular injection to lambs and by subcutaneous injection only to ewes. Calves and piglets may be administered by intramuscular injection only.

### **8. WITHDRAWAL PERIOD**

Piglets, Lambs, Calves: Meat – Zero days.

Ewes : Meat – 28 days.

### **9. SPECIAL WARNING(S), IF NECESSARY**

The product should not be administered to ewes producing milk for human consumption.

Care should be taken to avoid accidental self-injection.

Shake well before use.

Further information (including dose): See Package Leaflet.

## 10. EXPIRY DATE

D.O. M.:

Exp.:

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

Once broached use by: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light.

Keep container in outer carton.

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

[Not on label]

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

**For animal treatment only.**

POM-V

To be supplied only on veterinary prescription

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

**Keep out of the reach and sight of children.**

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

**Manufacturer:**

Norbrook Laboratories Limited  
Newry  
Co. Down  
Northern Ireland

**Distributed by:**

1 Saxon Way East  
Oakley Hay Industrial Estate  
Corby  
Northamptonshire  
NN18 9EX  
United Kingdom

**16. MARKETING AUTHORISATION NUMBER(S)**

ManA 2000  
Vm 02000/4115

**17. MANUFACTURER'S BATCH NUMBER**

B.N.:

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

[Include information under these headings as it appears in the SPC]

**PACKAGE LEAFLET FOR:**

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

**Manufactured by:**

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

**Distributed by:**

Norbrook Laboratories (GB) Limited  
1 Saxon Way East  
Oakley Hay Industrial Estate  
Corby  
Northamptonshire  
NN18 9EX  
United Kingdom

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

Vitesel Emulsion for Injection

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

Alpha-Tocopheryl Acetate	68 mg/ml
Selenium (as Potassium Selenate)	1.5 mg/ml
Benzyl alcohol as antimicrobial preservative	20 mg/ml

**4. INDICATION(S)**

Vitesel Injection is indicated for the prevention and treatment of Vitamin E-Selenium deficiency syndrome in piglets, lambs and calves, including various manifestations of nutritional muscular dystrophy (White Muscle Disease). Administration of Vitesel to the pregnant ewe may assist in the prevention of the deficiency syndrome of new born lambs under similar conditions.



## 5. CONTRAINDICATIONS

Hypersensitivity reactions, particularly in cattle, have occasionally been reported following use of this product. In such an event, symptomatic treatment should be undertaken as appropriate.

## 6. ADVERSE REACTIONS

Injection site reactions may occur in some animals. These are usually of a transient nature and diminish after a few days.

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

## 7. TARGET SPECIES

Piglets, lambs, calves and ewes

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

Administer by subcutaneous or intramuscular injection to lambs and by subcutaneous injection only to ewes and by intramuscular injection only to calves and piglets.

<b><u>SPECIES</u></b>	<b><u>DOSAGE</u></b>
Ewes:	(For protection of lambs against deficiency). 2 ml per 45 kg (100 lb) after third month of pregnancy.
New Born Lambs:	0.5 ml. Repeat after 2-4 weeks if required.
Older Lambs:	0.5 - 1.0 ml. Repeat after 2 - 4 weeks if required.
Calves:	1 - 2 ml per 45 kg (100 lb) bodyweight. Repeat after 2 - 4 weeks if required.
Piglets:	1ml per 25kg (55lb) bodyweight. Repeat after 2-4 weeks if required.

## 9. ADVICE ON CORRECT ADMINISTRATION

Normal aseptic precautions should be observed. Shake well before use

## 10. WITHDRAWAL PERIOD(S)

Piglets, Lambs, Calves: Meat – Zero days.

Ewes : Meat – 28 days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25°C.

Protect from light.

Keep container in outer carton.

## 12. SPECIAL WARNING(S)

Care should be taken to avoid accidental self-injection.

The product should not be administered to ewes producing milk for human consumption.

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

When the container is breached for the first time, the date on which any product remaining in the container should be calculated. This discard date should be written in the space provided on the label.

For Animal Treatment Only.

## 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

March 2012

## 15. OTHER INFORMATION>

**Marketing Authorisation No:**  
Vm 02000/4115

Multidose vials of 50 ml.

POM-V

To be supplied only on veterinary prescription

**Approved: 12/05/2017**

