

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

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

Anivit 4BC Solution for Injection

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

Anivit 4BC is a pale yellow to brown sterile solution for injection containing four members of the B-complex vitamins together with vitamin C.

Thiamine hydrochloride (Vitamin B <sub>1</sub> )	3.5% w/v
Riboflavine sodium phosphate (Vitamin B <sub>2</sub> )	0.05% w/v
Pyridoxine hydrochloride (Vitamin B <sub>6</sub> )	0.7% w/v
Nicotinamide	2.3% w/v
Ascorbic acid (Vitamin C)	7.0% w/v
Chlorocresol (preservative)	0.1% w/v

### **3. PHARMACEUTICAL FORM**

Solution for injection

### **4. PACKAGE SIZE**

Solution for injection

### **5. TARGET SPECIES**

Horses  
Cattle  
Sheep

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

Anivit 4BC may be used in the following cases:

- 1) Wherever deficiency of vitamin B group is suspected in horses, cattle and sheep.
- 2) In treatment of cerebrocortical necrosis in cattle and sheep.
- 3) In treatment of bracken poisoning in horses.

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

Administer by subcutaneous, deep intramuscular or slow intravenous injection. The dose should be repeated daily as required. Normal aseptic precautions should be observed.

<u>SPECIES</u>	<u>DOSAGE</u>
Horses, cattle	20 - 30 ml
Calves, foals	5 - 10 ml
Sheep	5 - 10 ml

If dose volume exceeds 20ml, it should be divided into two sites.

## **8. WITHDRAWAL PERIOD**

Meat; zero days

Milk: zero hours

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

Anaphylactoid reactions, particularly in the horse may occur following intravenous administration. When this route is used Anivit 4BC should be given slowly and may be diluted with sterile saline or sterile dextrose saline solution. This may be achieved by drawing sterile diluting solution into a syringe, followed by the required volume of Anivit 4BC. The diluted product must be administered immediately after preparation and must not be stored. Aseptic precautions should be observed. There may be slight irritation at the site of injection when the product is given by the subcutaneous or intramuscular routes.

Keep container in outer carton.

## **USER WARNINGS**

Care should be taken to avoid accidental self-injection. Wash hands after use.

## **10. EXPIRY DATE**

EXP:

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Protect from light.

Keep out of the reach of children.

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

## **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**

POM-VPS

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**

**Distributed by:**

Animalcare Ltd  
10 Great North Way  
York  
YO26 6RB

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

Vm 02000/4219

**17. MANUFACTURER’S BATCH NUMBER**

B.N.:

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

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

Anivit 4BC Solution for Injection

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

Thiamine hydrochloride (Vitamin B <sub>1</sub> )	3.5% w/v
Riboflavine sodium phosphate (Vitamin B <sub>2</sub> )	0.05% w/v
Pyridoxine hydrochloride (Vitamin B <sub>6</sub> )	0.7% w/v

Nicotinamide	2.3% w/v
Ascorbic acid (Vitamin C)	7.0% w/v
Chlorocresol (Preservative)	0.1% w/v

### 3. PHARMACEUTICAL FORM

Solution for Injection

### 4. PACKAGE SIZE

50 ml and 100 ml.

### 5. TARGET SPECIES

Horses  
Cattle  
Sheep

### 6. INDICATION(S)

For the treatment of cerebrocortical necrosis in cattle and sheep, the treatment of bracken poisoning in horses and for the treatment of Vitamin B deficiencies in horses, cattle and sheep.

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

For subcutaneous, intramuscular or slow intravenous injection. Dose should be repeated daily, as required.

Normal aseptic precautions should be observed.

Cattle, Horses	20 - 30 ml
Calves, Foals	5 - 10 ml
Sheep	5 - 10 ml

If dose volume exceeds 20ml, it should be divided into two sites.

### 8. WITHDRAWAL PERIOD

Meat: zero days; Milk: zero hours

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

Once broached, use by:
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Further Information: See Package leaflet

### USER WARNINGS

Care should be taken to avoid accidental self-injection. Wash hands after use.

## **10. EXPIRY DATE**

Exp: dd/mm/yy

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Protect from light.

Keep container in outer carton.

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

## **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.**

**POM-VPS**

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**

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

ManA 2000  
Vm 02000/4219

## **17. MANUFACTURER’S BATCH NUMBER**

B.N.:  
DOM:

### **Distributed by:**

Animalcare Ltd  
10 Great North Way  
York  
YO26 6RB



**PACKAGE LEAFLET FOR:**  
Anivit 4BC 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,  
Station Works,  
Newry, Co Down,  
BT35 6JP  
Northern Ireland

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

Anivit 4BC Solution for Injection

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

Anivit 4BC is a pale yellow to brown sterile solution for injection containing four members of the B-complex vitamins together with vitamin C.

Thiamine hydrochloride (Vitamin B <sub>1</sub> )	3.5% w/v
Riboflavine sodium phosphate (Vitamin B <sub>2</sub> )	0.05% w/v
Pyridoxine hydrochloride (Vitamin B <sub>6</sub> )	0.7 % w/v
Nicotinamide	2.3% w/v
Ascorbic acid (Vitamin C)	7.0% w/v
Chlorocresol (preservative)	0.1% w/v

**4. INDICATION(S)**

Anivit 4BC may be used in the following cases:

- 1) Wherever deficiency of vitamin B group is suspected in horses, cattle and sheep.
- 2) In treatment of cerebrocortical necrosis in cattle and sheep.
- 3) In treatment of bracken poisoning in horses.

**5. CONTRAINDICATIONS**

Anaphylactoid reactions, particularly in the horse may occur following intravenous administration. When this route is used Anivit 4BC should be given slowly and may be diluted with sterile saline or sterile dextrose saline solution. This may be achieved by drawing sterile diluting solution into a syringe, followed by the required volume of Anivit 4BC. The diluted product must be administered immediately after preparation and must not be stored. Aseptic precautions should be observed. There may be slight irritation at the site of injection when the product is given by the subcutaneous or intramuscular routes.

**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  
Cattle  
Sheep

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

Administer by subcutaneous, deep intramuscular or slow intravenous injection. The dose should be repeated daily as required.

<u>SPECIES</u>	<u>DOSAGE</u>
Horses, cattle	20 - 30 ml
Calves, foals	5 - 10 ml
Sheep	5 - 10 ml

## 9. ADVICE ON CORRECT ADMINISTRATION

Normal aseptic precautions should be observed.  
If dose volume exceeds 20ml, it should be divided into two sites.

## 10. WITHDRAWAL PERIOD(S)

Withdrawal periods: Meat: zero days; Milk: zero hours

## USER WARNINGS

Care should be taken to avoid accidental self-injection. Wash hands after use.

## 11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.  
Protect from light.  
Keep out of the reach and sight of children.  
Keep container in outer carton.  
Following withdrawal of the first dose, use the product within 28 days. Discard 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 carton should be discarded should be worked out. This discard date should be written in the space provided.

## 12. SPECIAL WARNING(S)

## 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**

July 2013

**15. OTHER INFORMATION**

Multidose vials of 50 ml and 100 ml.

**FOR ANIMAL TREATMENT ONLY**

POM-VPS

To be supplied only on veterinary prescription

Vm 02000/4219

**DISTRIBUTED BY:**

Animalcare Ltd  
10 Great North Way  
York  
YO26 6RB

**Approved: 25/07/2017**

