

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

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

Dunlop's 4BC Vitamin Solution for Injection

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

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

Each ml contains:

Thiamine Hydrochloride (Vitamin B <sub>1</sub> )	3.5 %w/v
Riboflavin 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**

Multidose vials of 50 ml and 100 ml.

### **5. TARGET SPECIES**

Horses, Cattle and Sheep

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

Dunlop's 4BC Vitamin Injection 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. If dose volume exceeds 20 ml it should be divided and injected into two sites.

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

### **USER WARNINGS:**

Care should be taken to avoid accidental self-injection.

Wash hands after use.

## **8. WITHDRAWAL PERIOD**

Withdrawal period for meat and milk: Zero days/hours

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

Anaphylactoid reactions, particularly in the horse may occur following intravenous administration. When this route is used Dunlop's 4BC Vitamin Injection 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 Dunlop's 4BC Vitamin Injection. 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.

## **10. EXPIRY DATE**

EXP: DD/MM/YY

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Protect from light.

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

Keep container in outer carton.

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 insert. This discard date should be written in the space provided on the primary label.

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

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in the farm refuse. Used containers should not be recycled

**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**

**MANUFACTURED BY:**

Norbrook Laboratories Limited

Newry

Co. Down

Northern Ireland

**DISTRIBUTED BY:**

W & J Dunlop Ltd

College Mains Road

Dumfries

Scotland

DG2 OBS

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

ManA 2000

VM: 02000/4177

**17. MANUFACTURER'S BATCH NUMBER**

B.N.:

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

LOGO

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

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

Dunlop's 4BC Vitamin Solution for Injection

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

Each ml contains:

Thiamine Hydrochloride (Vitamin B <sub>1</sub> )	3.5 %w/v
Riboflavin 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**

50ml and 100ml

### **5. TARGET SPECIES**

Horses, Cattle and Sheep

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

None

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

Solution of injection, 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

## **8. WITHDRAWAL PERIOD**

meat/milk – Zero days/hours

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

### **USER WARNINGS:**

Care should be taken to avoid accidental self-injection.

Wash hands after use.

## **10. EXPIRY DATE**

EXP: DD/MM/YY

Once broached, discard by: \_\_\_\_\_

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Protect from light.

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

Keep container in outer carton.

Further Information: See Package Leaflet

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

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in the farm refuse. Used containers should not be recycled.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF**

**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**

**Manufactured by:**

Norbrook Laboratories Limited

Newry

Co. Down,

Northern Ireland

**Distributed by:**

W & J Dunlop Ltd

College Mains Road

Dumfries

Scotland

DG2 OBS

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

ManA 2000

Vm 02000/4177

**17. MANUFACTURER'S BATCH NUMBER**

B.N.:

DOM:

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

PHARMVET™



**PACKAGE LEAFLET FOR: DUNLOP'S 4BC VITAMIN 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

Northern Ireland

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

Dunlop's 4BC Vitamin Solution for Injection

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

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

Each ml contains:

Thiamine Hydrochloride (Vitamin B <sub>1</sub> )	3.5 %w/v
Riboflavin 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)**

Dunlop's 4BC Vitamin Injection 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**

## **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 and 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 20 ml it should be divided and injected into two sites.

### **USER WARNINGS:**

Care should be taken to avoid accidental self-injection.

Wash hands after use.

## **10. WITHDRAWAL PERIOD(S)**

Withdrawal period for meat and milk: Zero days/hours

## **11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C.

Protect from light.

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

Keep container in outer carton.

Keep out of the reach and sight of children.

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 insert. This discard date should be written in the space provided on the primary label.

## **12. SPECIAL WARNING(S)**

Anaphylactoid reactions, particularly in the horse may occur following intravenous administration. When this route is used Dunlop's 4BC Vitamin Injection 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 Dunlop's 4BC Vitamin Injection. 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.

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

Rinse containers thoroughly with water. Dispose of rinsings in slurry or dirty water. Dispose of rinsed containers in the farm refuse. Used containers should not be recycled.

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

September 2008

## **15. OTHER INFORMATION>**

### **DISTRIBUTED BY:**

W & J Dunlop Ltd

College Mains Road

Dumfries

Scotland

DG2 OBS

### **Package Quantities:**

Multidose vials of 50 ml and 100 ml.

Not all pack sizes may be marketed.

BN:

D.O.M:

Exp: DD/MM/YY

ManA 2000

Vm 02000/4177

POM-VPS

To be supplied only on veterinary prescription

**FOR ANIMAL TREATMENT ONLY**

LOGO

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

**Approved: 24/08/2017**

