

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Dunlop's 4 BC Vitamin Solution for Injection.

### 2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Dunlop's 4BC Vitamin Injection contains:

#### ***Active Substance***

Thiamine Hydrochloride.	3.5 %w/v
Riboflavin Sodium Phosphate	0.05 %w/v
Pyridoxine Hydrochloride	0.7 %w/v
Nicotinamide	2.3 %w/v
Ascorbic Acid	7.0 %w/v

#### ***Excipients***

Chlorocresol (as preservative) 0.1 %w/v

For a full list of excipients, see section 6.1

### 3. **PHARMACEUTICAL FORM**

Solution for injection

A clear pale yellow liquid.

### 4. **CLINICAL PARTICULARS**

#### 4.1 ***Target species:***

Horses

Cattle

Sheep

#### 4.2 ***Indications for use, specifying the target species:***

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.

#### 4.3 ***Contraindications:***

None.

#### 4.4 ***Special Warnings for Each Target Species:***

None

4.5 ***Special Precautions for Use:***

**Special Precautions for use in animals:**

None

**Special precautions to be taken by the person administering the product to the animals:**

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

4.6 ***Adverse reactions (frequency and seriousness):***

Anaphylactic reactions, particularly in the horse, may occur following intravenous administration. When this route is used, the product should be given slowly and may be diluted with sterile saline or dextrose saline solution.

There may be slight irritation at the injection site when the product is given by the subcutaneous or intramuscular routes.

4.7 ***Use during pregnancy, lactation or lay:***

Can be safely administered to pregnant and lactating animals.

4.8 ***Interactions with other medicinal products and other forms of interaction:***

None.

4.9 ***Amount to be administered and administration route:***

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

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

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

4.10 ***Overdose (symptoms, emergency procedures, antidotes) (if necessary):***

Water soluble vitamins have a very high safety margin.

4.11 ***Withdrawal periods:***

Meat : Zero days  
Milk : Zero hours

5. **PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Vitamin B-complex, with vitamin C

ATCvet Code: QA11EB

5.1 ***Pharmacodynamic properties:***

Thiamine Hydrochloride (Vitamin B1) acts as a co-enzyme in the breakdown of glucose and glycogen. Riboflavin Sodium Phosphate (Vitamin B2) is phosphorylated to form the co-enzymes Riboflavin-5-phosphate and Flavin Adenine Dinucleotide (FAD) which act as hydrogen recipients and donors.

Pyridoxine Hydrochloride (Vitamin B6) is converted to pyridoxal phosphate which functions as a co-enzyme with the transaminases and decarboxylases in the metabolism of proteins and amino acids. Nicotinamide is converted into the essential co-enzymes Nicotinamide Adenine Dinucleotide (NAD) and Nicotinamide Adenine Dinucleotide Phosphate (NADP).

Vitamin C (Ascorbic Acid) is involved in the conversion of folic acid to tetrahydrofolic acid and the conversion of proline to hydroxyproline which is essential to the formation of collagen.

6. **PHARMACEUTICAL PARTICULARS**

6.1 ***List of excipients:***

Chlorocresol  
Disodium Edetate Dihydrate  
Propylene Glycol  
Sodium Hydroxide  
Water for Injections

6.2 ***Incompatibilities:***

None known

6.3 ***Shelf-life:***

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: 28 days.

6.4 ***Special precautions for storage:***

Protect from light. Do not store above 25°C.  
Following withdrawal of first dose use within 28 days.  
Discard unused material.

6.5 ***Nature and composition of immediate packaging:***

Dunlop's 4BC Vitamin Injection is marketed in 50 ml and 100 ml amber Type II glass vials, sealed with bromobutyl bungs and aluminium caps. Not all pack sizes may be marketed.

6.6 ***Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate:***

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

7. **MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited  
Station Works  
Camlough Road  
NEWRY  
Co. Down, BT35 6JP  
Northern Ireland

8. **MARKETING AUTHORISATION NUMBER**

Vm 02000/4177

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

21<sup>st</sup> December 1998

10. **DATE OF REVISION OF THE TEXT**

November 2008