

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Dunlop's 40 CM Solution for Injection

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

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

Contains Calcium Borogluconate 40% w/v and Magnesium Hypophosphite Hexahydrate 5% w/v.

#### ***Each 400 ml contains:***

11.9g calcium (provided by calcium gluconate and calcium borogluconate) and 1.85g magnesium (provided by magnesium hypophosphite).

Also contains 6.84% w/v boric acid.

#### ***Excipients:***

For a full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Solution for Injection  
A clear pale yellow solution

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle

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

Indicated in the treatment of hypocalcaemia in cattle where increased blood magnesium levels are required.

#### **4.3 Contraindications**

None

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

Care should be taken to avoid accidental self-injection: may cause irritation at site of injection.

#### **4.5 Special Precautions for Use**

i. Special Precautions for use in animals

The solution should be warmed to body temperature before administration. Intravenous injections should be given slowly in order to avoid possible neuromuscular dysfunction and cardiac insufficiency. Normal aseptic precautions should be observed. Sites of subcutaneous administration should be massaged gently.

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

None

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

Occasional temporary swelling may occur at sites of subcutaneous administration.

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

Safe for use during pregnancy and lactation

#### **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 or slow intravenous injection

Cattle : 200 - 400 ml

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

Not applicable.

#### **4.11 Withdrawal periods**

Cattle

Meat : Zero days

Milk : Zero hours

## **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Mineral supplements, Calcium, Calcium, combinations with other drugs

**ATCVet Code:** QA12AX

### **5.1 Pharmacodynamic properties**

Calcium Borogluconate and Magnesium Hypophosphite are soluble salts of calcium and magnesium respectively used extensively in fluid infusions in correction of metabolic disturbances. On parenteral administration they rapidly increase plasma concentrations of calcium, magnesium and phosphorus. This is effective in the treatment of hypocalcaemia with associated magnesium and phosphorus deficiencies.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium Bicarbonate 10% or (for pH adjustment)  
Boric Acid 5% (for pH adjustment)  
Water for Injections

### **6.2 Incompatibilities**

None known

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale:  
Glass bottles: 2 years.  
Polypropylene vials: 18 months

### **6.4 Special precautions for storage**

Do not store above 25°C. Protect from light.

This product does not contain an antimicrobial preservative. Any product remaining in the bottle after withdrawal of the first dose should be discarded.

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

Marketed in either 400 ml Amber Type III glass vials sealed using black rubber wads and aluminium screw caps, or 400ml natural polypropylene (Appryl 3020 SM3) vial sealed with bromobutyl bungs and aluminium caps.

**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** 02000/4216

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

5<sup>th</sup> July 1999

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

June 2010