# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject 40 Solution For Injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

***Active Substance:***

Each 400ml contains:-
11.88g Calcium provided by Calcium Gluconate and Calcium Borogluconate.
Also contains 6.5% w/v Boric Acid.

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

For the treatment of hypocalcaemia in cattle

### 4.3 Contraindications

None

### 4.4 Special Warnings for each target species

None

### 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. Observe aseptic precautions

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

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

## 4.6 Adverse reactions (frequency and seriousness)

Provided the recommendations are followed carefully, undesirable effects should not occur.

## 4.7 Use during pregnancy, lactation or lay

Calciject 40 can be safely administered to pregnant and lactating animals.

## 4.8 Interaction with other medicinal products and other forms of interaction

No known interactions.

## 4.9 Amounts to be administered and administration route

Administer by subcutaneous or slow intravenous injection at the following rate:

Cattle : 150 - 500 ml

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

Not applicable.

## 4.11 Withdrawal period

Meat : Zero days
Milk : Zero hours

# 5. PHARMACOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Mineral supplements, Calcium

**ATC Vet Code:** QA12AA

## 5.1 Pharmacodynamic properties

Milk fever which is characterised by hypocalcaemia is caused by an acute drop in the level of ionised calcium. Administration of calcium borogluconate by subcutaneous or slow intravenous injection replenishes plasma calcium levels and reverses the hypocalcaemia.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Boric Acid or Sodium Bicarbonate
Water for Injections

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as package for sale: 3 years

### 6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
The product does not contain an antimicrobial preservative. The product is intended for single use only. Any product remaining in the bottle after withdrawal of the required dose should be discarded

### 6.5 Nature and composition of immediate packaging

Calciject 40 is marketed in either 400 ml Amber Type III glass vials sealed with black rubber wads and aluminium screw caps, or 400 ml polypropylene containers sealed with grey bromobutyl bungs and aluminium caps.
Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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(S)

**Vm** 02000/4069

## 9. DATE OF FIRST AUTHORISATION

19th March 1986

## 10. DATE OF REVISION OF THE TEXT

June 2010