SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject 20 CMD Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Contains Calcium Borogluconate 20% w/v, Magnesium Hypophosphite Hexahydrate 5% w/v and Glucose Monohydrate 22% w/v.

Each 400ml contains:

5.92g calcium (provided by calcium gluconate and calcium borogluconate), 1.84g magnesium (provided by magnesium hypophosphate hexahydrate) and 80g glucose as glucose monohydrate. Also contains 3.40% w/v boric acid.

Excipients:
Chlorocresol 0.10

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

Sheep

4.2 Indications for use, specifying the target species

For the treatment of hypocalcaemia complicated by deficiency of magnesium with accompanying hypoglycaemia. In the treatment of pregnancy toxaemia and other metabolic imbalances in periparturient sheep.

4.3 Contraindications

Not to be administered by intravenous or intramuscular routes.

4.4 Special Warnings for each target species

No special warning.

4.5 Special precautions for use

(i) Special precautions for use in animals

The solution should be warmed to body temperature before administration.

(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.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

The solution should be warmed to body temperature before administration by subcutaneous injection only. Observe aseptic precautions.

Sheep: 50 - 80 ml

Message site gently after administration.

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

Not applicable.

4.11 Withdrawal period

Sheep:	Meat – Zero days Milk – Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Metabolic Preparation

ATC Vet Code: QA12AX

5.1 Pharmacodynamic properties

Milk fever, characterised by hypocalcaemia is caused by an acute drop in the level of calcium in the blood. At parturition hypophosphataemia and hypomagnesaemia can also occur. Administration by subcutaneous injection replenishes plasma concentrations of calcium, phosphate and magnesium ions. Dextrose is included as an energy source to coincide with the high turnover of energy during lambing.

5.2 Pharmacokinetic properties

The absorption of magnesium takes place in the proximal small intestine by active transport in a common pathway with calcium. Magnesium ions are inefficiently absorbed from the gastro-intestinal tract where absorption may be enhanced by the presence of vitamin D. Magnesium salts are excreted mainly in the urine with small amounts in milk, saliva and faeces. The normal range for magnesium in large animals is 1.7-3.0mg/100ml and clinical signs appear when the level drops below 1.0mg/100ml.

Blood glucose concentrations in healthy animals are closely controlled and in hyperglycaemia the excess blood glucose is normally removed from the circulation. The removal occurs by several routes including renal clearance: The renal threshold of blood glucose is readily exceeded.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium Bicarbonate
Water for Injections

6.2 Incompatibilities

None Known.

6.3.1 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: Glass Bottles: 2 years, Polypropylene vials: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.3.2 Special precautions for storage

(1) Once a vial has been broached the contents should be used within 28 days
(2) Do not store above 25°C.
(3) Protect from light.

6.5 Nature and composition of immediate packaging

A clear, pale yellow aqueous solution packed in either 400 ml amber type III glass bottles, with natural rubber wads and aluminium screw caps or 400 ml polypropylene vials with bromobutyl bungs and aluminium overseal.

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
Newry
Co. Down, BT35 6JP

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4189

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd May 2000/23rd May 2005

10. DATE OF REVISION OF THE TEXT

13 March 2008