SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dunlop's 20% w/v PMD Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Contains Calcium Gluconate	16.6% w/v
Magnesium Hypophosphite Hexahydrate	5% w/v
Glucose Monohydrate	22.0% w/v

Each 400 ml contains:

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

Excipients:

Chlorocresol	0.1% w/v

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection
A clear, pale yellow aqueous 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.
If accidental self-injection occurs, seek medical advice. Wash hands after use.

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 known

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. Sites of administration should be massaged gently.

Sheep: 50 - 80 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, Calcium, combinations with other drugs

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. When administered by subcutaneous injection the product 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium Bicarbonate (for pH adjustment)
Water for Injection

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:

Amber Glass Bottles	2 years.
Polypropylene Vials	2 years.

Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

(1) Following withdrawal of the first dose use the contents within 28 days. Discard unused material.
(2) Do not store above 25°C.
(3) Protect from light.

6.5 Nature and composition of immediate packaging

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 overseals

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 02000/4206

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd May 2000

10. DATE OF REVISION OF THE TEXT

July 2010