

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject 40 + 3 Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Calcium gluconate	332 mg
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Boric acid	68 mg
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Magnesium hypophosphite hexahydrate	30 mg
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For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

The product is indicated in the treatment of hypocalcaemia complicated by deficiency of magnesium.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The solution should be warmed to body temperature before administration. Intravenous injections should be given slowly and stopped on the first signs of adverse reaction. Rapid intravenous injection may result in cardiac arrhythmias and, in severely toxæmic animals, collapse and death. As intravenous administration of this product could cause death, this route should only be used by a veterinary surgeon.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Administer by subcutaneous or slow intravenous injection

Cattle: 150 - 400 ml

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

Not applicable.

4.11 Withdrawal period(s)

Meat: Nil

Milk: Nil

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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. The product is administered by subcutaneous or slow intravenous injection replenishes plasma concentrations of calcium, phosphate and magnesium ions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Hydrogen Carbonate
Water for Injection

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

400 ml Type III glass vials (amber) which are sealed using rubber wads (black) and aluminium screw caps or 400 ml polypropylene containers sealed with bromobutyl bungs (grey) 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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/032/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1991
Date of last renewal: 01 October 2006

10 DATE OF REVISION OF THE TEXT

December 2018