1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calciject 40 Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Calcium borogluconate	400.0 mg/ml
(Equivalent to calcium gluconate	332.0 mg/ml)
(Equivalent to calcium	29.6 mg/ml)
Boric Acid	68.0 mg/ml

Excipients:

Qualitative composition of excipients and other constituents
Sodium Bicarbonate
Water for Injections

A clear pale yellow sterile aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in the treatment of hypocalcaemia.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The solution should be warmed to body temperature before administration. Intravenous injections should be given slowly and stopped at the first signs of adverse reaction. Rapid intravenous injection may result in cardiac arrhythmias and in severely toxaemic 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 veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Administer by subcutaneous or slow intravenous injection.
Cattle: 150 - 400 ml

For single use only. Any unused material should be discarded after opening.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.
Milk: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QA12AA

4.2 Pharmacodynamics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

400 ml polypropylene containers with bromobutyl bungs (grey) and aluminium caps.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22664/031/001

8. DATE OF FIRST AUTHORISATION

01 October 1991

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

07 June 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).