

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcitat 50, solution for infusion and injection in cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml of solution contains:

Active Substances

Calcium gluconate monohydrate	3.10 g
Calcium borogluconate	42.90 g
Calcium hydroxide	1.32 g
Magnesium chloride hexahydrate	6.50 g

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E219)	0.10 g
2-Aminoethyl dihydrogen phosphate	
Macrogol 200	
Water for injections	

A clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

Paresis resulting from hypocalcaemia before, during and after parturition or during lactation. Downer cow syndrome.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in animals suffering from hypercalcaemia, hyperparathyroidism, acidosis, severe kidney damage.

3.4 Special warnings

Caution must be exercised when this veterinary medicinal product is used intravenously. As intravenous administration of this product could cause death, this route should only be used by a veterinary surgeon.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

None.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from available data):	Cardiac distress ¹
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¹Transient, following rapid intravenous infusion.

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 its local representative 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

Can be used during pregnancy and lactation. Most clinical indications occur at this time.

3.8 Interaction with other medicinal products and other forms of interaction

The use of admixtures should be avoided because of possible incompatibility with other substances in solution.

3.9 Administration routes and dosage

Intravenous or subcutaneous use.

Dosage: Cattle: 200 - 220 ml / 500 kg body weight.

Intravenous - administer slowly and at body temperature. Monitor cardiac performance during administration.

Subcutaneous - divide large volumes into several injection sites.

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

Symptoms of overdose would be cyanosis, dyspnoea, prostration, terminal excitement and ventricular fibrillation.

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 :

QA12AA03.

QA12CC01.

4.2 Pharmacodynamics

Replacement therapy to supply calcium as a corrective for hypocalcaemia for the treatment of milk fever, parturient paresis and similar conditions. Calcitat 50 is a complex of calcium-magnesiumgluconic acid and boric acid, supplemented with phosphorylethanolamine stimulating metabolism.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C.
Do not store below 8 °C.

5.4 Nature and composition of immediate packaging

Colourless glass bottle (HK2) with bromobutyl rubber stopper and an aluminium cap. Pack sizes:

1 x 100 ml, 12 x 100 ml

Sterile plastic bottle (Type PP28) with chlorobutyl rubber stopper and an aluminium cap.

Pack sizes:

1 x 250 ml, 1 x 500 ml and 60 x 250 ml

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

AniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10826/001/002

8. DATE OF FIRST AUTHORISATION

01/10/1999

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

13/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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