Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcitat 50, solution for infusion and injection in cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml 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	
Methyl parahydroxybenzoate (E219)	0.10 g

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for infusion and injection.

A clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Bovine.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

Intravenous - administer slowly and at body temperature. Monitor cardiac performance during administration.
Subcutaneous - divide large volumes into several injection sites.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Rapid intravenous infusion may result in transient cardiac distress.

4.7 Use during pregnancy, lactation or lay

The product may safely be used during pregnancy and lactation and most clinical indications occur at this time.

4.8 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.

4.9 Amounts to be administered and administration route

Administer by intravenous or subcutaneous injection.
Dosage: Cattle: 200-220ml / 500 kg body weight

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

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

4.11 Withdrawal Period(s)

Meat and offal: zero days.
Milk: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group and ATC vet code:

Alimentary tract and metabolism, mineral supplements, calcium gluconate. QA12AA03.
Alimentary tract and metabolism, mineral supplements, magnesium chloride. QA12CC01.

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-magnesium-gluconic acid and boric acid, supplemented with phosphorylethanolamine stimulating metabolism.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

2-Aminoethyl dihydrogen phospate
Methyl Parahydroxybenzoate (E219)
Macrogol 200
Water for Injections

6.2 Incompatibilities

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

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

100 ml
Vial: 100 ml HK2 colourless glass bottle
Stopper: Bromobutyl rubber stopper
Cap: Aluminium cap

250 and 100 ml
Vial: 250 or 500 ml sterile plastic bottles (Type PP28)
Stopper: Chlorobutyl rubber stopper
Cap: Aluminium cap

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10826/001/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT