SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Addimag 160 mg/ml + 84 mg/ml solution for infusion for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Calcium gluconate monohydrate 160 mg
(equivalent to 14.3 mg or 0.36 mmol calcium)
Magnesium chloride hexahydrate 84 mg
(equivalent to 10.0 mg or 0.41 mmol magnesium)

Excipients:
Boric acid (E284) 32 mg
Glucose monohydrate 110 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion
Clear, yellow to brownish solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

For the treatment of clinical hypomagnesaemia (grass tetany) accompanied by deficiency of calcium and for the treatment of clinical hypocalcaemia (milk fever) complicated by deficiency of magnesium.

4.3 Contraindications

Do not use in cases of hypercalcaemia and hypermagnesemia.
Do not use in cases of calcinosis in cattle.
Do not use following administration of high doses of vitamin D3.
Do not use in cases of chronic kidney insufficiency or in cases of circulatory or cardiac disorders.
Do not use in cases of septicaemic processes in the course of acute mastitis in cattle.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The medicinal product must be administered slowly, at body temperature.
During infusion, the heart rate, rhythm and circulation must be monitored. In case of symptoms of overdosing (bradycardia, cardiac arrhythmia, fall in blood pressure, agitation), the infusion should be stopped immediately.

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

Not applicable

4.6 Adverse reactions (frequency and seriousness)

Too rapid administration of the product may cause the following effects:
Calcium may cause a transient hypercalcaemia with the following symptoms: initial bradycardia followed by tachycardia, arrhythmia (especially ectopic ventricular beats), muscle tremors, salivation and increased respiratory rate. Increase in heart rate following initial bradycardia may indicate that overdosing has occurred. In this case the administration should be stopped immediately.

4.7 Use during pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Calcium increases the efficacy of cardiac glycosides and arrhythmias may occur if these drugs are given together.
Calcium amplifies the cardiac effects of β-adrenergic drugs and methylxanthines.
Glucocorticoids increase the renal excretion of calcium by way of vitamin D antagonism.
Do not administer inorganic phosphate solutions simultaneously or shortly after the infusion.

4.9 Amounts to be administered and administration route

Slow intravenous use.
These dosage instructions are given for guidance and must be adapted to the individual deficit and actual circulatory conditions.
Administer approximately 15 - 20 mg Ca^{2+} (0.37 – 0.49 mmol Ca^{2+}) and 10 – 13 mg Mg^{2+} (0.41 - 0.53 mmol Mg^{2+}) per kg bodyweight corresponding to approximately 1.0 - 1.4 ml of product per kg bodyweight.

If the animal's weight cannot be determined accurately, but has to be estimated, the following approach might be used:

Bottle size (ml)	Weight (kg)	Ca^{2+} (mg/kg)	Mg^{2+} (mg/kg)
500	350-475	15.1 – 20.4	10.5 – 14.3
750	500-725	14.8 – 21.5	10.3 – 15.0

The intravenous infusion must be executed slowly over a period of 20-30 minutes.

After a minimum of 6 hours after treatment, a second treatment may be administered. The administration can be repeated twice at 24-hour intervals, if the hypocalcaemic condition is persisting.

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

When the intravenous administration is performed too rapidly, hypercalcaemia and/or hypermagnesemia with cardiotoxic symptoms such as initial bradycardia with subsequent tachycardia, cardiac arrhythmia and in severe cases ventricular fibrillation with cardiac arrest may occur.
Additional symptoms of hypercalcaemia are: motor weakness, muscle tremors, increased excitability, agitation, sweating, polyuria, fall in blood pressure, depression and coma.
Symptoms of hypercalcaemia may persist 6 – 10 hours after the infusion and must not be incorrectly diagnosed as symptoms of hypocalcaemia.

4.11 Withdrawal periods

Meat and offal: Zero days
Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Calcium, combinations with vitamin D and/or other drugs.
ATC vet code: QA12AX

5.1 Pharmacodynamic properties

Calcium
Calcium is an essential element that is required for normal nerve and musculoskeletal function, cell membrane and capillary permeability and activation of enzymatic reactions. Only free ionised calcium in the blood is biologically active.

Magnesium
Magnesium is a cofactor in a number of enzyme systems. It also plays a role in muscular excitement and neurochemical transmission. In the heart magnesium leads to delayed conduction. Magnesium stimulates the secretion of parathyroid hormone and therefore regulates serum calcium levels.

5.2 Pharmacokinetic particulars

Calcium
Approximately 99% of total body calcium is found in bone and teeth. The remaining 1% is found mainly in the extra-cellular fluid. Of circulating calcium, approximately 50% is bound to serum proteins or complexed with anions and 50% is in the ionized form. Total serum calcium is dependent on serum protein concentrations. Calcium crosses the placenta and is distributed into milk. Calcium is eliminated mainly through the faeces with small amounts eliminated in the urine.

Magnesium
In adult animals, around 60% of magnesium is found in bone where it is relatively difficult to mobilize. Magnesium is about 30 – 35% bound to proteins and the remainder exists as free ions. It is excreted by the kidneys at a rate proportional to the serum concentration and glomerular filtration.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Boric acid (E-284)
Glucose monohydrate
Water for injections

6.2 Major incompatibilities

In the absence of compatibility 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: once broached, use immediately.

6.4 Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

500 and 750 ml square shaped clear polypropylene (PP) bottle with a bromobutyl rubber stopper and an aluminium screw cap.

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 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

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 36408/4003

9. DATE OF FIRST AUTHORISATION

01 March 2022

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 01 March 2022