ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

500 ml and 750 ml bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Addimag 240 mg/ml + 126 mg/ml solution for infusion for cattle
calcium gluconate monohydrate + magnesium chloride hexahydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Calcium gluconate monohydrate	240 mg/ml (equivalent to 21,5 mg or 0.54 mmol calcium)
Magnesium chloride hexahydrate	126 mg/ml (equivalent to 15.1 mg or 0.62 mmol magnesium)

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

500 ml
750 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Slow intravenous use
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Zero days
Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: once broached, use immediately.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Do not refrigerate or freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36408/4004

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Addimag 240 mg/ml + 126 mg/ml solution for infusion for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer responsible for batch release:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Bela-pharm GmbH & Co. KG
Lohner Str. 19
49377 Vechta
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Addimag 240 mg/ml + 126 mg/ml solution for infusion for cattle
calcium gluconate monohydrate + magnesium chloride hexahydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Calcium gluconate monohydrate 240 mg
(equivalent to 21,5 mg or 0.54 mmol calcium)
Magnesium chloride hexahydrate 126 mg
(equivalent to 15.1 mg or 0.62 mmol magnesium)

Excipients:
Boric acid (E-284) 48 mg
Glucose monohydrate 165 mg

Solution for infusion
Clear, yellow to brownish solution

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

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.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 0.7 - 0.9 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	500-725	14.8 – 21.5	10.4 – 15.1
750	750-1000	16.1 – 21.5	11.3 – 15.1

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIODS

Meat and offal: Zero days
Milk: Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C.
Do not refrigerate or freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: once broached, use immediately.

12. SPECIAL WARNING(S)

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

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.

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.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 500 ml and 750 ml.

Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 01 March 2022