PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box
Polypropylene bottle 12 x 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calmino vet, 380/60/50 mg/ml solution for infusion for cattle, sheep and pigs (UK)
calcium gluconate for injection
magnesium chloride hexahydrate
boric acid

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Calcium gluconate for injection	380 mg (equivalent to 34.0 mg or 0.85 mmol of Ca^{2+})
Magnesium chloride hexahydrate	60 mg (equivalent to 7.2 mg or 0.30 mmol of Mg^{2+})
Boric acid	50 mg

3. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

12 x 500 ml

5. TARGET SPECIES

Cattle, sheep, pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle, pigs, sheep:
Meat and offal: zero days.

Cattle, sheep:
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached: use immediately.

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Interchemie Werken De Adelaar Eesti AS
Vanapere tee 14, Püünsi
Viimsi rural municipality
Harju county 74013
Estonia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 51467/4000

17. MANUFACTURER'S BATCH NUMBER

Batch number:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Polypropylene bottle 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calmino vet, 380/60/50 mg/ml solution for infusion for cattle, sheep and pigs (UK)
calcium gluconate for injection
magnesium chloride hexahydrate
boric acid

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Calcium gluconate for injection	380 mg (equivalent to 34.0 mg or 0.85 mmol of Ca^{2+})
Magnesium chloride hexahydrate	60 mg (equivalent to 7.2 mg or 0.30 mmol of Mg^{2+})
Boric acid	50 mg

3. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle, sheep, pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle, pigs, sheep:

Meat and offal: zero days.

Cattle, sheep:
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once broached: use immediately.

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Interchemie Werken De Adelaar Eesti AS
Vanapere tee 14, Püünsi
Viimsi rural municipality
Harju county 74013
Estonia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 51467/4000

17. MANUFACTURER'S BATCH NUMBER

Batch number:

PACKAGE LEAFLET
Calmino vet, 380/60/50 mg/ml solution for infusion for cattle, sheep and pigs

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

Marketing authorisation holder and manufacturer responsible for batch release:
Interchemie Werken De Adelaar Eesti AS
Vanapere tee 14, Püünsi
Viimsi rural municipality
Harju county 74013
Estonia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calmino vet, 380/60/50 mg/ml solution for infusion for cattle, sheep and pigs
calcium gluconate for injection
magnesium chloride hexahydrate
boric acid

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

One ml contains:

Active substances:

Calcium gluconate for injection	380 mg (equivalent to 34.0 mg or 0.85 mmol of Ca^{2+})
Magnesium chloride hexahydrate	60 mg (equivalent to 7.2 mg or 0.30 mmol of Mg^{2+})
Boric acid	50 mg

Excipients:
Water for injections

Clear, colourless to yellowish brown solution.

4. INDICATION(S)

Treatment of acute hypocalcaemia 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 and sheep.
Do not use following administration of high doses of vitamin D_3.
Do not use in cases of chronic kidney insufficiency or in cases of circulatory or cardiac disorders.

Do not use in cattle suffering septicaemic processes in the course of acute mastitis in cattle.
Do not administer inorganic phosphate solutions simultaneously or shortly after the infusion.

6. ADVERSE REACTIONS

Calcium may cause a transient hypercalcaemia with the following symptoms: initial bradycardia (slow heart rate), agitation, muscle tremors, salivation, increase in respiratory rate.

Increase in heart rate following initial bradycardia may indicate that overdosing has occurred. In this case the administration should be stopped immediately. Delayed side effects, that can manifest as disorders of general condition, and symptoms of hypercalcaemia 6 – 10 hours after administration are not to be diagnosed as a recurring hypocalcaemia.

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.

Alternatively you can report via your national reporting system: *To be completed in accordance with national requirements after conclusion of the MR phase.*

7. TARGET SPECIES

Cattle, sheep, pigs.

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

For slow intravenous administration, recommended over a period of 20 – 30 minutes. The smaller volumes (less than 50 ml) should be administered by a sterile syringe or syringe infusion pump.

Cattle
Administer 14 – 20 mg Ca^{2+} (0.34 – 0.51 mmol Ca^{2+}) and 2.9 – 4.3 mg Mg^{2+} (0.12 – 0.18 mmol Mg^{2+}) per one kg bodyweight corresponding to 0.4 – 0.6 ml of product per 1 kg bodyweight.

Sheep, calf, pig
Administer 10 – 14 mg Ca^{2+} (0.26 – 0.34 mmol Ca^{2+}) and 2.2 – 2.9 mg Mg^{2+} (0.09 – 0.12 mmol Mg^{2+}) per one kg bodyweight corresponding to 0.3 – 0.4 ml of product per 1 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

For slow intravenous administration, recommended over a period of 20 – 30 minutes. The specified dosages are standard. The dose should always be adapted to the existing deficit and condition of the circulatory system.

The second treatment can be administered not earlier than 12 hours after the first administration. The administration can be repeated twice at 24-hour intervals, if the hypocalcaemic condition is persisting.

During the infusion, the heart rate, rhythm and circulation must be monitored. In cases of symptoms of overdosing (cardiac arrhythmia, fall in blood pressure, agitation), the infusion should be stopped immediately.

10. WITHDRAWAL PERIOD(S)

Cattle, pigs, sheep:
Meat and offal: zero days.

Cattle, sheep:
Milk: zero hours.

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species
In case of acute hypomagnesaemia, the administration of a solution with a higher concentration of magnesium may be necessary.

Special precautions for use in animals
The medicinal product must be administered only slowly intravenously.
The solution should be warmed to body temperature before administration.
During the infusion, the heart rate, rhythm and circulation must be monitored. In case of symptoms of overdosing (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
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal product contains boric acid, and should not be administered by pregnant women, users of childbearing age, and users trying to conceive.
This product can cause slight skin and eye-irritation due to the low pH of the product formulation.
Avoid contact with skin and eyes.
Wear protective gloves and glasses.

When the product comes into contact with the skin or eyes, rinse immediately with water.

Pregnancy and lactation
The safety of the 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 effects of heart glycosides.
Calcium amplifies the cardiac effects of β-adrenergic medicinal products and methylxanthines.
Glucocorticoids increase the renal excretion of calcium by way of vitamin D-antagonism.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

Package size: 500 ml or 12x500 ml in a cardboard box

Not all pack sizes may be marketed.