

LABELLING AND PACKAGE LEAFLET

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Outer Package /
Cardboard box for multi-unit packages, 6 x 500 ml, 12 x 500 ml}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcibel 240/60/60 mg/ml solution for infusion for horses, cattle, sheep, goats and pigs.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Calcium gluconate	240 mg	(equivalent to 21.5 mg calcium)
Magnesium chloride hexahydrate magnesium)	60 mg	(equivalent to 7.2 mg magnesium)
Boric acid	60 mg	

3. PACKAGE SIZE

6 x 500 ml
12 x 500 ml

4. TARGET SPECIES

Horse, cattle, sheep, goat, pig.

5. INDICATION(S)

[Not requested]

6. ROUTES OF ADMINISTRATION

For intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle, sheep, goats, horses:

Meat and offal:	Zero days
Milk:	Zero hours
Pig: Meat and offal:	Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use immediately

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG

14. MARKETING AUTHORISATION NUMBERS

Vm 41816/4002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle 500ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcibel 240/60/60 mg/ml solution for infusion for horses, cattle, sheep, goats and pigs.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Calcium gluconate	240 mg	(equivalent to 21.5 mg calcium)
Magnesium chloride hexahydrate magnesium)	60 mg	(equivalent to 7.2 mg
Boric acid	60 mg	

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Horse, cattle, sheep, goat, pig.

5. INDICATION(S)

[Not requested]

6. ROUTES OF ADMINISTRATION

For intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle, sheep, goats, horses:

Meat and offal:	Zero days
Milk:	Zero hours
Pig: Meat and offal:	Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use immediately

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co. KG

14. MARKETING AUTHORISATION NUMBERS

Vm 41816/4002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Calcibel
240/60/60 mg/ml solution for infusion in horses, cattle, sheep, goats and pigs

2. Composition

Each ml contains:

Active substance:

Calcium gluconate	240 mg	(equivalent to 21.5 mg calcium)
Magnesium chloride hexahydrate magnesium)	60 mg	(equivalent to 7.2 mg
Boric acid	60 mg	

Clear, colourless to slightly yellowish solution.

Osmolarity: 1,386 - 1,694 osmol/l
pH value: 3.2 - 4.0

3. Target species

Horse, cattle, sheep, goat, pig.

4. Indications for use

For the treatment of acute hypocalcaemia.

5. Contraindications

Do not use in cases of:

- hypercalcaemia and hypermagnesaemia,
- idiopathic hypocalcaemia in foals,
- calcinosis in cattle and small ruminants,
- septicaemia in the course of acute mastitis in cattle,
- chronic renal insufficiency or cases of circulatory or cardiac disorders.

Do not use following application of high doses of vitamin D3 preparations.

Do not use concomitantly or immediately following application of inorganic phosphorous solutions.

Do not use in cases of known hypersensitivity to the active substances.

6. Special warnings

Special warnings:

In case of acute hypomagnesaemia, the administration of a solution with a higher concentration of magnesium may be necessary.

Special precautions for safe use in the target species

During intravenous infusion, the product must be administered slowly and at body temperature.

During infusion, cardiac rate and rhythm and circulation must be monitored. If any sign of overdose (disturbances of the cardiac rhythm decrease in blood pressure, restlessness) appears, the infusion should be stopped immediately.

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

Care should be taken to avoid accidental self-injection as this may cause irritation at site of injection. In case of accidental self-injection, seek medical advice immediately and show the label to the physician.

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.

This veterinary medicinal product contains boric acid, and should not be administered by pregnant women and users trying to conceive.

Pregnancy and Lactation:

The safety of the veterinary medicinal product has not been established during lactation. Use only accordingly 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.

Calcium increases the cardiac effects of β -adrenergic drugs and methylxanthines.

Glucocorticoids increase the renal excretion of calcium by vitamin D antagonism.

Overdose:

Overdose and intravenous infusion that is too fast may result in initial bradycardia with subsequent tachycardia, cardiac rhythm disturbances and, in severe cases, ventricular fibrillation' with cardiac arrest. .

Additional symptoms of hypercalcaemia are: motor weakness, muscle tremors, increased excitability, agitation, sweating, polyuria, fall in blood pressure, depression and coma.

Exceeding the maximum infusion rate may result in hypersensitivity reactions due to the release of histamine. Symptoms of hypercalcaemia may persist for 6-10 hours after infusion. It is important that these symptoms are not incorrectly diagnosed as a relapse of hypocalcaemia.

Major incompatibilities

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

7. Adverse events

Horse, cattle, sheep, goat, pig

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	High calcium ¹ Slow heart rate ² Rapid Breathing ² Restlessness ² Muscle tremor ² Increased salivation ² Rapid heart rate ^{2,3} General illness ^{2,4}
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¹transient

²symptoms of high calcium

³after an initial slow heart rate it may indicate an overdose. In this case, stop the infusion immediately.

⁴can occur as a delayed adverse event and with symptoms of high calcium even 6 - 10 hours after the infusion and must not be misdiagnosed as a recurrence of low calcium. See also "Overdose".

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

UK

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

IE

HPRA Pharmacovigilance

Website: www.hpra.ie

8. Dosage for each species, routes and method of administration

Intravenous use.

Cattle:

For slow intravenous infusion.

Adult cattle:

40-50 ml of this product per 50 kg body weight
(equivalent to 17.2 – 21.5 mg Ca²⁺ and 5.8 – 7.2 mg Mg²⁺ per kg b.w.).

Calf:

30 ml of this product per 50 kg body weight
(equivalent to 12.9 mg Ca²⁺ and 4.3 mg Mg²⁺ per kg body weight).

Sheep, goat, pig:

For slow intravenous infusion.

30 ml of this product per 50 kg body weight
(equivalent to 12.9 mg Ca²⁺ and 4.3 mg Mg²⁺ per kg body weight).

Horse:

For slow intravenous infusion.

30 ml of this product per 50 kg body weight
(equivalent to 12.9 mg Ca²⁺ and 4.3 mg Mg²⁺ per kg body weight).

9. Advice on correct administration

Cattle, sheep, goats and pigs:

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

Horses:

Infusion in horses should not exceed a rate of 4-8 mg/kg/h calcium (equivalent to 0.18-0.36 ml/kg/h of this veterinary medicinal product). It is recommended to dilute the required dose of this veterinary medicinal product 1:4 with isotonic saline or dextrose and to infuse over at least two hours.

The dosage instructions are given for guidance and must be adapted to the individual deficit and actual circulatory conditions.

After a minimum of 6 hours after treatment, a second treatment may be administered. Additional treatments every 24 hours can be administered if it is clear that on-going symptoms are due to hypocalcaemia.

10. Withdrawal periods

Cattle, sheep, goats, horses:

Meat and offal:	Zero days
Milk:	Zero hours
Pig: Meat and offal:	Zero days

11. Special storage precautions

Keep out of the sight and reach of children.

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 immediate packaging: use immediately..

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 41816/4002

Pack sizes:

1 x 500 ml

6 x 500 ml

12 x 500 ml

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Bela-Pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany
Phone: +49 4441 8730
Email: info@bela-pharm.com

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

IE: Duggan Veterinary Supplies Ltd.
Unit 9,
Thurles Retail Park,
Thurles, Co Tipperary,
Ireland, E41 E7K7
Phone: +353 504 43169
Email: pv@dugganvet.ie

UK: DUGV(UK) Ltd.
Union House 111,
New Union Street, Coventry,
United Kingdom, CV1 2NT
Phone: +353 504 43169
Email: pv@dugganvet.ie

17. Other information

<p>UK Only Vm 41816/4002</p> <table border="1"><tr><td>POM-V</td></tr></table> <p>To be supplied only on veterinary prescription.</p>	POM-V
POM-V	

<p>IE Only VPA10445/003/001</p> <table border="1"><tr><td>POM</td></tr></table> <p>Prescription Only Medicine To be supplied only on veterinary prescription</p>	POM
POM	

B. COMBINED LABELLING

Full information of package leaflet and label are provided on the 500 ml bottle.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet

{Bottle 500ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcibel
240/60/60 mg/ml solution for infusion in horses, cattle, sheep, goats and pigs.

2. COMPOSITION

Each ml contains:

Active substance:

Calcium gluconate	240 mg	(equivalent to 21.5 mg calcium)
Magnesium chloride hexahydrate magnesium)	60 mg	(equivalent to 7.2 mg
Boric acid	60 mg	

Clear, colourless to slightly yellowish solution for infusion.

Osmolarity: 1,386 - 1,694 osmol/l
pH value: 3.2 - 4.0

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Horse, cattle, sheep, goat, pig.

5. INDICATIONS FOR USE

Indications for use

For the treatment of acute hypocalcaemia.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of:

- hypercalcaemia and hypermagnesaemia,
- idiopathic hypocalcaemia in foals,
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- septicaemia in the course of acute mastitis in cattle,

- chronic renal insufficiency or cases of circulatory or cardiac disorders.

Do not use following application of high doses of vitamin D3 preparations.

Do not use concomitantly or immediately following application of inorganic phosphorous solutions.

Do not use in cases of known hypersensitivity to the active substances.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

In case of acute hypomagnesaemia, the administration of a solution with a higher concentration of magnesium may be necessary.

Special precautions for safe use in the target species:

During intravenous infusion, the product must be administered slowly and at body temperature.

During infusion, cardiac rate and rhythm and circulation must be monitored. If any sign of overdose (disturbances of the cardiac rhythm decrease in blood pressure, restlessness) appears, the infusion should be stopped immediately.

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Interaction with other medicinal products and other forms of interaction:

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Overdose:

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8. ADVERSE EVENTS

Adverse events

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IE

HPRA Pharmacovigilance

Website: www.hpra.ie

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Intravenous use.

Cattle:

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10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Cattle, sheep, goats and pigs:

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After a minimum of 6 hours after treatment, a second treatment may be administered. Additional treatments every 24 hours can be administered if it is clear that on-going symptoms are due to hypocalcaemia.

11. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle, sheep, goats, horses:

Meat and offal: Zero days

Milk: Zero hours

Pig: Meat and offal: Zero days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems.

These measures should help to protect the environment.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 41816/4002

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1 x 500 ml

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17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Bela-Pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany
Phone: +49 4441 873 555
Email: info@bela-pharm.com

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

IE: Duggan Veterinary Supplies Ltd.
Unit 9,
Thurles Retail Park,
Thurles, Co Tipperary,
Ireland, E41 E7K7
Phone: +353 504 43169
Email: pv@dugganvet.ie

UK: DUGV(UK) Ltd.
Union House 111,
New Union Street, Coventry,
United Kingdom, CV1 2NT
Phone: +353 504 43169
Email: pv@dugganvet.ie

18. OTHER INFORMATION

UK Only Vm 41816/4002
<input type="text" value="POM-V"/>
To be supplied only on veterinary prescription.

IE Only VPA10445/003/001
<input type="text" value="POM"/>
Prescription Only Medicine To be supplied only on veterinary prescription

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: use immediately.

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 28 July 2025