

LABELLING AND PACKAGE LEAFLET

Note:

Depending on the conditions of the individual markets, the product will be marketed either with a combined label or with separate package leaflet and label.

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 Forte, 380/60/50 mg/ml solution for infusion for horses, cattle, sheep, goats and pigs.

2. COMPOSITION

1 ml contains:

Active substances:

| | | |
|--|--------|---------------------------------|
| Calcium gluconate for injection | 380 mg | (equivalent to 34.0 mg calcium) |
| Magnesium chloride hexahydrate magnesium) | 60 mg | (equivalent to 7.2 mg |
| Boric acid | 50 mg | |

Clear, slightly, yellow-brownish solution, free from visible particles

Osmolarity: 0.690 – 0.850 osmol/l

pH value: 3.0 - 4.0

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Horses, cattle, sheep, goats, pigs.

5. INDICATIONS FOR USE

Indications for use

Acute hypocalcaemic conditions.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypercalcaemia and hypermagnesemia.

Do not use in cases of idiopathic hypocalcaemia in foals.

Do not use in cases of calcinosis in cattle and small ruminants.

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 cattle suffering septicaemic processes in the course of acute mastitis in cattle.

Do not administer inorganic phosphate solutions simultaneously or shortly after the infusion.

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

7. SPECIAL WARNINGS

Special warnings

Special warnings:

None known.

Special precautions for safe use in the target species:

The veterinary medicinal product must be administered only slowly intravenously.

The solution should be warmed to body temperature before administration.

During infusion, 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:

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

Pregnancy:

The safety of the product has not been established during pregnancy. 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.

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

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

Overdose:

In case of overdose or if infusion has been carried out too rapidly, hypercalcaemia or hypermagnesaemia with cardiotoxic symptoms as initial bradycardia with subsequent tachycardia, disturbances of the cardiac rhythm, and in severe cases ventricular fibrillation may occur. Other symptoms of hypercalcaemia are: motoric weakness, muscle tremor, increased excitability, restlessness, transpiration, polyuria, decrease in blood pressure, depression and coma.

Exceeding the maximum infusion rate may result in hypersensitivity reactions due to the release of histamine.

If the symptoms described above are observed, the infusion has to be stopped immediately.

Symptoms of hypercalcaemia may persist for 6-10 hours after infusion. It is important that these symptoms are not incorrectly diagnosed as a recurring hypocalcaemia.

Major incompatibilities:

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

8. ADVERSE EVENTS

Adverse events

Horses, cattle, sheep, goats, pigs

| | |
|--|---|
| Very rare (<1 animal / 10,000 animals treated, including isolated reports): | Hypercalcaemia ¹ Bradycardia ² , tachycardia ³ Tachypnoea Restlessness Muscle tremors Hypersalivation General illness ⁴ |
|--|---|

¹Transient.

²Initially.

³Increase in heart rate following initial bradycardia may indicate overdose. In this case, stop the infusion immediately.

⁴Delayed undesirable effects may appear in form of disturbances of the general state of health and symptoms of hypercalcaemia up to 6 – 10 hours after administration and must not be diagnosed as recurring hypocalcaemia.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 on this label, or via your national reporting system at: Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine> e-mail: adverse.events@vmd.gov.uk

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

Dosage for each target species, routes and method of administration

For slow intravenous infusion

Cattle:

Acute hypocalcaemic conditions:

20-30 ml of this product per 50 kg body weight
(equivalent to 0.34 – 0.51 mmol Ca²⁺ and 0.12 – 0.18 mmol Mg²⁺ per kg body weight).

Horse, calf, sheep, goat, pig:

15-20 ml of this product per 50 kg body weight
(equivalent to 0.26 – 0.34 mmol Ca²⁺ and 0.09 – 0.12 mmol Mg²⁺ per kg body weight).

Infusion in horses should not exceed a rate of 4-8 mg/kg/h calcium (equivalent to 0.12-0.24 ml/kg/h of this product). It is recommended to dilute the required dose of this product 1:4 with isotonic saline or dextrose and to infuse over at least two hours.

Dosage instructions above serve as guidance, but must be adapted to the existing individual deficit and condition of the circulatory system.

After a minimum of 6 hours after treatment, a second treatment may be administered. Additional treatments every 24 hours can be administered if persisting symptoms are clearly related to due to hypocalcaemia.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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

11. WITHDRAWAL PERIODS

Withdrawal periods

| | |
|---|------------|
| Cattle, sheep, goats, horses: Meat and offal: | Zero days |
| Milk: | Zero hours |
| Pigs: 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 the 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 41816/4005

Pack sizes

1 x 500 ml

12 x 500 ml

Not all pack sizes may be marketed

16. 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.

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 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 listed below.

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

Other information

UK Only

Vm 41816/4005

POM-V

To be supplied only on
veterinary prescription.

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once broached, use immediately.

21. BATCH NUMBER

Lot {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcibel Forte, 380/60/50 mg/ml solution for infusion for horses, cattle, sheep, goats and pigs.

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:

| | | |
|---------------------------------|--------|----------------------------------|
| Calcium gluconate for injection | 380 mg | (equivalent to 34.0 mg calcium) |
| Magnesium chloride hexahydrate | 60 mg | (equivalent to 7.2 mg magnesium) |
| Boric acid | 50 mg | |

3. PACKAGE SIZE

12 x 500 ml

4. TARGET SPECIES

Horses, cattle, sheep, goats, pigs.

5. INDICATIONS

[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 |
| Pigs: | 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

Marketing authorisation holder

Bela-Pharm GmbH & Co. KG

14. MARKETING AUTHORISATION NUMBER

Vm 41816/4005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {500ml bottle}

This immediate package with a package leaflet might be used in case that a combined label is not possible due to space restriction in case of multilingual packages.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calcibel Forte, 380/60/50 mg/ml solution for infusion for horses, cattle, sheep, goats and pigs.

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:

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| Calcium gluconate for injection | 380 mg | (equivalent to 34.0 mg calcium) |
| Magnesium chloride hexahydrate | 60 mg | (equivalent to 7.2 mg magnesium) |
| Boric acid | 50 mg | |

3. PACKAGE SIZE

1 x 500 ml

4. TARGET SPECIES

Horses, cattle, sheep, goats, pigs.

5. INDICATIONS

[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 |
| Pigs: | 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 NUMBER

Vm 41816/4005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

This package leaflet in combination with an immediate label might be used in case that a combined label is not possible due to space restriction in case of multilingual packages.

1. Name of the veterinary medicinal product

Calcibel Forte, 380/60/50 mg/ml solution for infusion for horses, cattle, sheep, goats and pigs.

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Clear, slightly, yellow-brownish solution, free from visible particles.

Osmolarity: 0.690 – 0.850 osmol/l

pH value: 3.0 - 4.0

3. Target species

Horses, cattle, sheep, goats, pigs

4. Indications for use

Acute hypocalcaemic conditions.

5. Contraindications

Do not use in cases of hypercalcaemia and hypermagnesaemia.

Do not use in cases of idiopathic hypocalcaemia in foals.

Do not use in cases of calcinosis in cattle and small ruminants.

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 cattle suffering septicaemic processes in the course of acute mastitis in cattle.

Do not administer inorganic phosphate solutions simultaneously or shortly after the infusion.

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

6. Special warnings

Special warnings:

None known.

Special precautions for safe use in the target species:

The medicinal product must be administered only slowly intravenously.

The solution should be warmed to body temperature before administration.

During infusion, 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:

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

Pregnancy:

The safety of the product has not been established during pregnancy. 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.

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

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

Overdose:

In case of overdose or if infusion has been carried out too rapidly, hypercalcaemia or hypermagnesaemia with cardiotoxic symptoms as initial bradycardia with subsequent tachycardia, disturbances of the cardiac rhythm, and in severe cases ventricular fibrillation may occur. Other symptoms of hypercalcaemia are: motoric weakness, muscle tremor, increased excitability, restlessness, transpiration, polyuria, decrease in blood pressure, depression and coma.

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Symptoms of hypercalcaemia may persist for 6-10 hours after infusion. It is important that these symptoms are not incorrectly diagnosed as a recurring 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): | Hypercalcaemia ¹ Bradycardia ² , tachycardia ³ Tachypnoea Restlessness Muscle tremors Hypersalivation General illness ⁴ |
|---|---|

¹Transient.

²Initially.

³Increase in heart rate following initial bradycardia may indicate overdose. In this case, stop the infusion immediately.

⁴Delayed undesirable effects may appear in form of disturbances of the general state of health and symptoms of hypercalcaemia up to 6 – 10 hours after administration and must not be diagnosed as recurring hypocalcaemia.

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 at:

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

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

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

For slow intravenous infusion

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Infusion in horses should not exceed a rate of 4-8 mg/kg/h calcium (equivalent to 0.12-0.24 ml/kg/h of this product). It is recommended to dilute the required dose of this product 1:4 with isotonic saline or dextrose and to infuse over at least two hours.

The intravenous infusion must be executed slowly over a period of 20-30 minutes. Dosage instructions above serve as guidance, but must be adapted to the existing individual deficit and condition of the circulatory system. After a minimum of 6 hours after treatment, a second treatment may be administered. Additional treatments every 24 hours can be administered if persisting symptoms are clearly related to due to hypocalcaemia.

9. Advice on correct administration

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

10. Withdrawal periods

| | | |
|-------------------------------|-----------------|------------|
| Cattle, sheep, goats, horses: | Meat and offal: | Zero days |
| | Milk: | Zero hours |
| Pigs: | 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 the 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.

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 41816/4005

Pack sizes:

1 x 500 ml
12 x 500 ml

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

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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:

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 listed below.

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

UK Only
Vm 41816/4005

POM-V

To be supplied only
on veterinary

Approved 04 August 2025

Gavin Hall