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 PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

{NATURE/TYPE}

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

2. Name of the veterinary medicinal product

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

3. Statement of the active substance (s) and other ingredients

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	

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

4. Pharmaceutical form

Solution for infusion

5. Package size

500 ml

6. Indication(s)

Acute hypocalcaemic conditions.

7. 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.

8. Adverse reactions

Transient hypercalcaemia with the following symptoms has been reported very rarely in spontaneous reports:

- initial bradycardia,
- restlessness, muscle tremor, hypersalivation,
- increase in respiratory rate.

An increase of heart rate following an initial bradycardia may indicate overdose. In this case, stop the infusion immediately. Delayed 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.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 {national system details}.

9. Target species

Horses, cattle, sheep, goats, pigs.

10. Dosage for each species, route(s) 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 Ca^{2+} and 0.12 – 0.18 mmol Mg^{2+} 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 Ca^{2+} and 0.09 – 0.12 mmol Mg^{2+} 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.

11. Advice on correct administration

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

12. Withdrawal period(s)

Withdrawal periods:

Cattle, sheep, goats, horses:	Meat and offal:	Zero days
	Milk:	Zero hours
Pigs:	Meat and offal:	Zero days

13. Special storage precautions

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.
Do not refrigerate or freeze.

14. Special warning(s)

Special warnings for each target species:
None known.

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 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, lactation and lay:
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 (symptoms, emergency procedures, antidotes):
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.

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

15. 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.

16. Date on which the label was last approved

17. Other information

Pack sizes:
1 x 500 ml
12 x 500 ml

Not all pack sizes may be marketed

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

For animal treatment only.

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

Keep out of the sight and reach of children.

20. EXIRY DATE

EXP {month/year}

Once broached, use immediately.

21. MARKETING AUTHORISATION NUMBER(S)

Vm 41816/4005

22. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE LABELING
[Outer Package / Cardboard box for multi-unit packages]

12 x 500 ml

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. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

12 x 500 ml

5. TARGET SPECIES

Horses, cattle, sheep, goats, pigs.

6. INDICATION(S)

[Not requested]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle, sheep, goats, horses:	Meat and offal:	Zero days
	Milk:	Zero hours
Pigs:	Meat and offal:	Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry date: {month/year}
Once broached, use immediately

11. SPECIAL STORAGE CONDITIONS

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

Marketing authorisation holder
Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

Distributor
DUGV (UK) Ltd
Union House
111 New Union Street
Coventry
CV1 2NT
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41816/4005

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE LABELING
[Immediate Package]

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 x 500 ml

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. PHARMACEUTICAL FORM

Solution for infusion.

4. PACKAGE SIZE

1 x 500 ml

5. TARGET SPECIES

Horses, cattle, sheep, goats, pigs.

6. INDICATION(S)

[Not requested]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle, sheep, goats, horses:	Meat and offal:	Zero days
	Milk:	Zero hours
Pigs:	Meat and offal:	Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry date: {month/year}
Once broached, use immediately

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

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

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

Marketing authorisation holder
Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

Distributor
DUGV (UK) Ltd
Union House
111 New Union Street
Coventry
CV1 2NT
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41816/4005

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

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.

B. Package Leaflet

Package leaflet

Calcibel Forte, 380/60/50 mg/ml solution for infusion for horses, cattle, sheep, goats 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
Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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	

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

4. INDICATION(S)

Acute hypocalcaemic conditions.

5. 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.

6. ADVERSE REACTIONS

Transient hypercalcaemia with the following symptoms has been reported very rarely in spontaneous reports:

- initial bradycardia,
- restlessness, muscle tremor, hypersalivation,
- increase in respiratory rate.

An increase of heart rate following an initial bradycardia may indicate overdose. In this case, stop the infusion immediately. Delayed 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 a relapse of hypocalcaemia.
See also “Overdose”.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Horses, cattle, sheep, goats, pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 Ca^{2+} and 0.12 – 0.18 mmol Mg^{2+} 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 Ca^{2+} and 0.09 – 0.12 mmol Mg^{2+} 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.

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.

10. WITHDRAWAL PERIOD(S)

Cattle, sheep, goats, horses:	Meat and offal:	Zero days
	Milk:	Zero hours
Pigs:	Meat and offal:	Zero days

11. SPECIAL STORAGE PRECAUTIONS

Once broached, use immediately.
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.

12. SPECIAL WARNING(S)

Special warnings for each target species
None known.

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 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.

Use during pregnancy, lactation or lay
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 (symptoms, emergency procedures, antidotes), if necessary
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.

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

{DD/MM/YYYY}

15. OTHER INFORMATION

Pack sizes:
1 x 500 ml
12 x 500 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.

Local representative:
DUGV (UK) Ltd
Union House
111 New Union Street
Coventry
CV1 2NT
United Kingdom

Distributor
DUGV (UK) Ltd
Union House
111 New Union Street
Coventry
CV1 2NT
United Kingdom

Approved 02 November 2021