[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kaltetan forte 458.4 mg/ml + 125 mg/ml + 20 mg/ml solution for infusion for horses, cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Calcium gluconate for injection 458.4 mg
(equivalent to 40.97 mg calcium, or 1.02 mmol of Ca^{2+})

Magnesium chloride hexahydrate 125 mg
(equivalent to 14.94 mg magnesium, or 0.61 mmol of Mg^{2+})

Sodium glycerophosphate pentahydrate 20 mg
(equivalent to 2.02 mg phosphorus, or 0.07 mmol of P^{5+})

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Boric acid	60 mg
Water for injections	

Clear, yellow to brownish solution.
pH of the solution 3.0 – 4.0
Osmolality 5200 – 6400 mOsmol/kg

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs

3.2 Indications for use for each target species

Treatment of electrolyte disorders in mammals (calcium deficiencies are usually accompanied by magnesium and phosphorus deficiencies):
Horses: clinical form of hypocalcaemia
Cattle: clinical form of hypocalcaemia i.e. milk fever (paresis before or after parturition, periparturient paresis) and grass tetany (clinical form of hypomagnesaemia)
Pigs: clinical form of hypocalcaemia (paresis before or after parturition, periparturient paresis)

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances, or to any of the excipients.
Do not use in cases of hypercalcaemia and hypermagnesemia, idiopathic hypocalcaemia in foals, in cases of calcinosis in ruminants.
Do not use in hyperactive animals.
Do not use in cases of chronic kidney insufficiency or in cases of circulatory or cardiac disorders.

Do not use in case of septicaemic processes in the course of acute mastitis in cattle.
Do not use following administration of high doses of vitamin D_3. Do not use concomitant or immediately following application of inorganic phosphorous solutions.

3.4 Special warnings

In case of acute hypomagnesemia (grass tetany) in cattle, additional supplementation of magnesium is recommended.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The solution should be warmed up to body temperature before administration.
The veterinary medicinal product must be administered slowly to avoid adverse reactions such as loss of balance and arrhythmia. During the intravenous infusion the cardiac and respiratory function should be monitored (by auscultation).

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

This veterinary medicinal product contains boric acid, and should not be administered by pregnant women, users of childbearing age, and users trying to conceive.
Handle the veterinary medicinal product with care to avoid accidental self-injection.
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 can cause slight skin and eye irritation due to the low pH of the product formulation. Avoid contact with skin and eyes. When the veterinary medicinal product comes into contact with the skin or eyes, rinse immediately with water.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses, cattle, pigs:

Undetermined frequency (cannot be estimated from the available data):	Application site reaction[1,3] Arrhythmia (with subsequent tachycardia)[2,3], bradycardia[2,3]

[1] Phlebitis and/or blood clotting. In order to avoid these conditions intravenous catheters should be used.
[2] In case of too fast administration of the veterinary medicinal product. In this case administration should be stopped until the symptoms resolve. During the infusion, the heart rate, rhythm must be monitored.
[3] In cattle adverse reactions may appear shortly after administration (up to 30 minutes) or be delayed from 6-7 hours up to 6 days after administration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies have shown evidence that boric acid affects fertility and development. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product should not be used concomitantly with other products due to possible interactions. In particular concurrent administration with the following substances should be avoided: tetracyclines, sodium carbonate, streptomycin, dihydrostreptomycin sulfate. Cardiac glycosides, sympathomimetics or methylxantines administered simultaneously with the veterinary medicinal product can enhance toxic effect of the calcium on the heart. Administration of Vitamin D_3 preparation concurrently may lead to the local tissue calcinosis, especially in case of undiagnosed hypomagnesaemia.

3.9 Administration routes and dosage

Intravenous use.
Infusion must be administered slowly (not faster than 20 ml of the product per 1 minute).
The smaller volumes should be administered by a syringe infusion pump.
The recommended dosages are:

Cattle, Horses:	160 ml
Calves:	15 ml
Pigs:	40 ml

There is assumed that the calcium safe dose is 12 mg of Ca/kg of body weight. However sometimes in case of persistent symptoms of calcium deficiency increase of the volume administered is necessary. The volume should not exceed 0.4 ml/kg of the body weight (which corresponds to 16 mg/kg of the body weight) in one infusion. Special warnings for use of the veterinary medicinal product should be taken into account.

Depending on severity of clinical signs the administration of the veterinary medicinal product may be repeated until the clinical signs resolve.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Multiple administration of doses higher than recommended, as well as too fast administration may cause nausea, muscles weakness, tachycardia following initial bradycardia and arrhythmia and even allergic reaction. If any sign of overdose appears, the infusion should be stopped immediately.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Horses, cattle, pigs:
Meat and offal: Zero days.

Horses, cattle:
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA12AX

4.2 Pharmacodynamics

Calcium is one of the most important chemical elements in the organism of humans and animals, necessary for maintaining suitable structure of bones and teeth. In addition, it plays an important role in muscle contraction process and in many other biochemical processes, such as blood clotting, nerve conduction or muscle cell function. Calcium in the form of gluconate is thought to be particularly effective in the treatment of hypocalcemia.
Magnesium like calcium is a macroelement of high biological importance.
It acts as a coenzyme in many enzymatic reactions, especially those associated with the transport of high-energy phosphates. In addition, it stimulates neuromuscular transmission (by preventing the occurrence of paroxysmal tonic-clonic and tetanus contractions), inhibits the release of acetylcholine in the neuromuscular junction, stimulates the secretion of parathormon and is involved in the regulation of calcium metabolism. There is a remarkable dependency between calcium and magnesium. Calcium acts antagonistic to magnesium effect on cardiac and neuromuscular activity. Hypomagnesaemia as single condition is rarely observed. Most often it is connected with calcium and phosphate deficiencies, the symptoms of which often mask the symptoms of hypomagnesemia.
Sodium glycerophosphate is a source of phosphate, supporting treatment of calcium and phosphorus metabolism imbalances. Glycerophosphate is a high-energy factor mediating catabolic and anabolic reactions, plays an important role in fat metabolism, mediates the biosynthesis of phosphatidylcholines and lecithins, is also a substrate for phosphatases.
In the course of hypocalcaemia, parathyroid hormone (PTH) increases the secretion of phosphorus in urine and saliva, which makes it difficult to determine the actual level of phosphorus and which causes hypophosphataemia along with hypocalcemia.

4.3 Pharmacokinetics

Ninety-nine percent of body calcium is found in the skeleton. The remaining 1% is mainly located in extracellular space of which approx. 40% is bound to plasma proteins while approx. 50% is in the form of easily soluble ions. The mean concentration of calcium in the blood plasma ranges between 2.0 and 2.8 mmol/l. Calcium is mainly excreted via faeces, because 90% of the total quantity reaching the kidneys is reabsorbed in the renal tubules. In addition, calcium is able to cross placenta barriers and to pass into milk.
Magnesium mainly occurs in bones (50%), intracellularly (45%) and in extracellular fluid (5%). One-third of magnesium found in blood serum is bound to plasma proteins. It is mainly excreted via urine. The normal level of magnesium in the blood plasma is 0.75-1.1 mmol/1.
Phosphorus in the form of glycerophosphate is also easily absorbed after parenteral administration, being a typical and naturally occurring intermediate product in metabolic transformations. During the hydrolysis, glycerophosphate is transformed into non-organic phosphate, which penetrates into the blood serum, extracellular fluids, cell membranes, intracellular fluid, collagen, osseous tissue and milk. With the urine are excreted more than 90% of phosphates of which about 80% is actively reabsorbed in the kidney. While parathyroid hormones stimulate the secretion of phosphate via the urine by blocking reabsorption, vitamin D and its metabolites directly enhance phosphate reabsorption in the renal tubules. The normal level of non-organic phosphate in the blood plasma is 1.4-2.3 mmol/1.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 27 months.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Polypropylene (PP) bottles closed with a bromobutyl rubber stopper, type I and secured with an aluminium cap.
Package size:
500 ml bottle.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vet-Agro Multi-Trade Company Sp. z o.o.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Veterinary medicinal product not subject to prescription. (LT)

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Calcium gluconate for injection 458.4 mg
(equivalent to 40.97 mg calcium, or 1.02 mmol of Ca^{2+})

Magnesium chloride hexahydrate 125 mg
(equivalent to 14.94 mg magnesium, or 0.61 mmol of Mg^{2+})

Sodium glycerophosphate pentahydrate 20 mg
(equivalent to 2.02 mg phosphorus, or 0.07 mmol of P^{5+})

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Horses, cattle, pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Horses, cattle, pigs:
Meat and offal: Zero days.

Horses, cattle:
Milk: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

{Logo name of the marketing authorisation holder}

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Kaltetan forte 458.4 mg/ml + 125 mg/ml + 20 mg/ml solution for infusion for horses, cattle and pigs

2. Composition

Each ml contains:

Active substances:

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(equivalent to 40.97 mg calcium, or 1.02 mmol of Ca^{2+})

Magnesium chloride hexahydrate 125 mg
(equivalent to 14.94 mg magnesium, or 0.61 mmol of Mg^{2+})

Sodium glycerophosphate pentahydrate 20 mg
(equivalent to 2.02 mg phosphorus, or 0.07 mmol of P^{5+})

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Boric acid	60 mg

Clear, yellow to brownish solution.
pH of the solution 3.0 – 4.0
Osmolality 5200 – 6400 mOsmol/kg

3. Target species

Horses, cattle, pigs

4. Indications for use

Treatment of electrolyte disorders in mammals (calcium deficiencies are usually accompanied by magnesium and phosphorus deficiencies):
Horses: clinical form of hypocalcaemia
Cattle: clinical form of hypocalcaemia i.e. milk fever (paresis before or after parturition, periparturient paresis) and grass tetany (clinical form of hypomagnesaemia)
Pigs: clinical form of hypocalcaemia (paresis before or after parturition, periparturient paresis)

5. Contraindications

Do not use in cases of hypersensitivity to the active substances, or to any of the excipients.
Do not use in cases of hypercalcaemia and hypermagnesemia, idiopathic hypocalcaemia in foals, in cases of calcinosis in ruminants. Do not use in hyperactive animals.
Do not use in cases of chronic kidney insufficiency or in cases of circulatory or cardiac disorders.

Do not use in case of septicaemic processes in the course of acute mastitis in cattle.
Do not use following administration of high doses of vitamin D_3. Do not use concomitant or immediately following application of inorganic phosphorous solutions.

6. Special warnings

Special warnings:

In case of acute hypomagnesemia (grass tetany) in cattle, additional supplementation of magnesium is recommended.

Special precautions for safe use in the target species:

The solution should be warmed up to body temperature before administration. The veterinary medicinal product must be administered slowly to avoid adverse reactions such as loss of balance and arrhythmia.
During the intravenous infusion the cardiac and respiratory function should be monitored (by auscultation).

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

This veterinary medicinal product contains boric acid, and should not be administered by pregnant women, users of childbearing age, and users trying to conceive.
Handle the veterinary medicinal product with care to avoid accidental self-injection.
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 can cause slight skin and eye irritation due to the low pH of the product formulation. Avoid contact with skin and eyes. When the veterinary medicinal product comes into contact with the skin or eyes, rinse immediately with water.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies have shown evidence that boric acid affects fertility and development. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

The veterinary medicinal product should not be used concomitantly with other products due to possible interactions. In particular concurrent administration with the following substances should be avoided: tetracyclines, sodium carbonate, streptomycin, dihydrostreptomycin sulfate. Cardiac glycosides, sympathomimetics or methylxantines administered simultaneously with the veterinary medicinal product can enhance toxic effect of the calcium on the heart. Administration of Vitamin D_3 preparation concurrently may lead to the local tissue calcinosis, especially in case of undiagnosed hypomagnesaemia.

Overdose:

Multiple administration of doses higher than recommended, as well as too fast administration may cause nausea, muscles weakness, tachycardia following initial bradycardia and arrhythmia and even allergic reaction. If any sign of overdose appears, the infusion should be stopped immediately.

Major incompatibilities:

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

7. Adverse events

Horses, cattle, pigs:

Undetermined frequency (cannot be estimated from the available data):	Application site reaction[1,3] Arrhythmia (with subsequent tachycardia)[2,3], bradycardia[2,3]

[1] Phlebitis and/or blood clotting. In order to avoid these conditions intravenous catheters should be used.
[2] In case of too fast administration of the veterinary medicinal product. In this case administration should be stopped until the symptoms resolve. During the infusion, the heart rate, rhythm must be monitored.
[3] In cattle adverse reactions may appear shortly after administration (up to 30 minutes) or be delayed from 6-7 hours up to 6 days after administration.

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: {national system details}

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

Intravenous use.
The smaller volumes should be administered by a syringe infusion pump.
The recommended dosages are:

Cattle, Horses:	160 ml
Calves:	15 ml
Pigs:	40 ml

There is assumed that the calcium safe dose is 12 mg of Ca/kg of body weight. However sometimes in case of persistent symptoms of calcium deficiency increase of the volume administered is necessary. The volume should not exceed 0.4 ml/kg of the body weight (which corresponds to 16 mg/kg of the body weight) in one infusion. Special warnings for use of the veterinary medicinal product should be taken into account.

Depending on severity of clinical signs the administration of the veterinary medicinal product may be repeated until the clinical signs resolve.

9. Advice on correct administration

Infusion must be administered slowly (not faster than 20 ml of the product per 1 minute).

10. Withdrawal periods

Horses, cattle, pigs:
Meat and offal: Zero days.

Horses, cattle:
Milk: Zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

Veterinary medicinal product not subject to prescription. (LT)

14. Marketing authorisation numbers and pack sizes

Package size:
500 ml bottle.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32, 20-616 Lublin
Poland

Contact details to report suspected adverse reactions:

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.

17. Other information