SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Kalciumklorid Abboxia 0.46 mmol/ml solution for injection, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains calcium chloride dihydrate corresponding to 18.3 mg calcium.
Contains 0.46 mmol/ml calcium and 0.91 mmol/ml chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection, solution

Clear, colourless to slightly coloured solution.

pH: 5.5-7.5

Osmolarity: approx 1200 mOsm/kg

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

”Invented name” is used to treat hypocalcaemia, calcium channel blocker overdose, hypermagnesemia or hyperkalaemia in adults and children.

4.2 Posology and method of administration

Posology
”Invented name” 0.46 mmol/ml solution for injection is administered as a slow intravenous injection. It should be noted that ”Invented name” 0.46 mmol/ml solution for injection must not be administered subcutaneously or intramuscularly.

Adults
Intravenous injection: 5-10 ml is given as a slow intravenous injection over 5-10 min. The dose may be repeated if necessary.

Children
Intravenous injection: 0.1-0.3 ml/kg of bodyweight as a slow intravenous injection over (5-10 min). The dose may be repeated if necessary.

Patients with renal impairment
There is insufficient experience from the use of ”Invented name” in treating patients with renal impairment. Therefore, patients with severe renal impairment should not be treated with ”Invented name”(see section 4.3).

Patients with liver impairment
There is insufficient experience from the use of ”Invented name” in treating patients with liver

impairment. Therefore, it is not possible to provide specific recommendations for treating these patients with calcium chloride.

Monitoring:
Treament with ”Invented name” 0.46 mmol/ml solution for injection as parenteral administration should always be accompanied with a close monitoring of the blood concentration and urine excretion of calcium. Ionized calcium should be monitored to prevent hypercalcemia. Plasma concentrations exceeding 1.30 mmol/ml should be counted as hypercalcemia. Intravenous administration of calcium should be followed by checking of heart frequency and ECG since bradycardia with vasodilation or arrythmia may occur if calcium is administered too quickly. It may also be necessary to monitor the neuromuscular function.

Method of administration
Intravenous administration.
”Invented name” 0.46 mmol/ml solution for injection should preferably be administered in a central venous catheter due to vascular irritation and risk of necrosis during extravasation. When administered into a peripheral vein, careful monitoring should be carried out to ensure that extravasation is avoided when injecting calcium chloride.

4.3 Contraindications

- Hypersensitivity to calcium chloride or any of the excipients listed in section 6.1.
- Hypercalcemia, hypercalciuria, hypophosphatemia, severe kidney disease.
- Ventricular fibrillation.
- Kidney stone since this condition may be worsened.
- Concurrent administration of ceftriaxone, see section 4.5.
- Patients given digitalis glycosides or adrenaline, see section 4.5

4.4 Special warnings and precautions for use

Overtreatment of hypocalcemia should be avoided.

Caution should be taken when ”Invented name” is administered in patients with sarcoidosis as it may increase the hypercalcemia which occurs in this condition.

Addition of calcium to sepsis patients has not proven to be beneficial for the patient and may cause harm.

Take precautions to avoid extravasation when intravenous injection is performed. Calcium chloride may cause severe necrotizing tissue damage.

Intravenous administration of calcium chloride may cause vasodilatation, which may result in a moderate blood pressure fall.

Caution should be taken when administrating intravenous calcium solutions since there is an increased risk of hypercalcemia in conditions such as chronic renal impairment, dehydration or electrolyte imbalance.

Caution should be taken when administrating intravenous calcium solutions in patients with cardiac disease since calcium salts may increase the risk of cardiac arrhythmia.

Calcium chloride acidifies and caution should be taken when administration is performed in conditions when acidification may cause issues such as in renal disease, cor pulmonale, respiratory acidosis and respiratory failure.

Calcium should not be given solely but together with an ongoing glucose drip (without calcium, phosphorus or magnesium) when administration is performed via peripheral infusion lines.

”Invented name” solution for injection must not be given in the same infusion line as other solutions containing calcium, such as nutrition solutions. Calcium chloride is irritating and should not be given intramuscularly, subcutaneously or in perivascular tissue since severe necrosis may occur. Direct injection into the heart tissue should be avoided.

There is a risk of precipitation when concurrent intravenous administration of calcium chloride and phosphate or magnesium is performed, see section 6.2. The precipitation may stick in small blood vessels and gives rise to emboli.

Continuous ECG monitoring should be performed when using calcium salts, to counteract cardiac toxicity in connection with hypercalcemia.

The serum concentrations of calcium should be closely monitored in patients with renal impairment, especially in concomitant treatment with high doses of vitamin D. Frequent monitoring of S-calcium levels is recommended during the treatment to assure that normal levels are not exceeded. Monitoring of the calcium concentrations in the urine may also be necessary to avoid hypercalciuria which may occur in presence of hypocalcemia.

4.5 Interaction with other medicinal products and other forms of interaction

Ceftriaxone
Concurrent administration of calcium and ceftriaxone is contraindicated; this also applies when using different infusion lines due to the risk of ceftriaxone-calcium precipitations. For children 28 days or younger there must be 48 hours between administration of ceftriaxone and calcium respectively. For children older than 28 days the infusion line should be thoroughly rinsed with NaCl 9 mg/ml between each infusion of ceftriaxone and calcium respectively, or different infusion lines should be used.

Cardiac glycosides/digitalis
Since the inotropic and toxic effects of intravenously administered calcium chloride and cardiac glycosides are synergistic, concurrent use may increase the risk of arrhythmia.

Adrenaline
Concurrent use of calcium and adrenaline may result in arrythmia.

Calcium channel blockers
Calcium may reduce the effect of verapamil when used concurrently. This probably also applies to other calcium channel blocking agents.

Calcium containing or magnesium containing medicinal products
Concurrent use with other calcium-containing or magnesium-containing medicinal products may increase the risk of hypercalcemia or hypermagnesemia, especially in patients with renal disease.

Neuromuscular blocking agents
Concurrent use with parenteral calcium salts usually reverses the effects of nondepolarizing neuromuscular blocking agents; also, concurrent use with calcium salts has been reported to enhance or prolong the neuromuscular blocking action of tubocurarine.

Thiazide diuretics
The combination of calcium with thiazide diuretics may induce hypercalcemia since these medicinal products reduce the renal extraction.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies are insufficient in respect to reproduction toxicity (see section 5.3). Published data is insufficient regarding use during pregnancy.

Breastfeeding
Published data is insufficient regarding use during breastfeeding.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

”Invented name” has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects which may occur are shown below in accordance with MedDRA-classification of system organ classes. Most adverse reactions are dose dependent.

Cardiovascular and other systemic adverse reactions in the table may occur as a symptom of acute hypercalcemia, because of a rapid intravenous injection or overdose, see section 4.9.

MedDRA system organ class	**Adverse event**	**Frequency**
Cardiac disorders	Bradycardia	Not known
	Arrhythmia	Not known
	Syncope	Not known
Blood and lymphatic system disorders	Blood pressure fall	Not known
	Peripheral vasodilation	Not known
Gastrointestinal disorders	Constipation	Not known
	Abdominal pain	Not known
	Nausea	Not known
	Vomiting	Not known
General disorders and administration site conditions	Local reactions such as skin redness or rash and pain at extravasation which may lead to severe necrosis	Not known
	Heat sensation, calcinosis cutis	Not known

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V

4.9 Overdose

Symptoms
Hypercalcemia may occur when high doses of calcium salts are given, especially in patients with renal failure. Symptoms associated with hypercalcemia include thirst, nausea, vomiting, constipation, polyuria, abdominal pain, muscle weakness, mental disturbances and, in severe cases, cardiac arrhythmia and coma.

Treatment
Plasma concentrations of ionized calcium exceeding 1.30 mmol/L are considered as hypercalcemia. Plasma concentrations of calcium should be monitored at frequent intervals to guide therapy.

For mild cases of overdose, treatment involves immediately discontinued administration of calcium chloride and other calcium-containing medicinal products.

- For more serious cases the following measures may be required to reduce the plasma calcium concentration: Intravenous rehydration with NaCl.
- Use of non-thiazide diuretics
- Dialysis for very serious or life-threatening overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Blood substitutes and perfusion solutions, i.v. solutions, ATC code: B05BB01

Calcium is essential for the function of the nervous system, muscles, heart, cell membranes, skeleton, as well as capillary permeability. Calcium plays an important role in many enzymatic reactions, and it is essential for several physiological processes. This includes transmission of nerve impulses, contraction of heart muscle, smooth muscle, and skeletal muscles. Calcium is also essential for kidney function, respiration, and blood clotting. Calcium also plays a regulating role in the release and storage of neurotransmitters and hormones. Calcium also plays a regulating role in the uptake and binding of amino acids, in cyanocobalamin absorption and in gastrin secretion.

Calcium in the skeleton is in constant exchange with calcium in plasma. Plasma calcium concentrations are kept within narrow limits by means of an endocrine control mechanism involving parathyroid hormone, calcitonin and vitamin D. With this control mechanism, calcium can be released from the bones if plasma calcium levels decrease and can be bound to the bones if plasma calcium levels rise.

5.2 Pharmacokinetic properties

Absorption
Calcium salts administered intramuscularly or intravenously are absorbed directly in the blood circulation.

Distribution
99% of total body calcium is contained in the bones and teeth. Approximately 50% of calcium in serum plasma is in the physiologically active, ionised form, 5% is complexed with phosphates, citrates and other anions. Approximately 45% of serum calcium is bound to plasma proteins (principally albumin).

Biotransformation
Injected calcium becomes a part of the body’s own intravascular calcium and is metabolised in the same way as the body’s own calcium.

Elimination
Calcium is excreted via faeces, urine and sweat. The renal excretion if dependent on the glomerular filtration and the tubular reabsorption of calcium.

5.3 Preclinical safety data

There are no preclinical data which are assessed as relevant for the clinical safety beyond data in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

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

Tetracyclines
Calcium salts may form complexes with tetracyclines and therefore tetracyclines and calcium salts should not be mixed for parenteral administration.

Magnesium sulphate
Mixing calcium salts with magnesium sulfate may cause precipitation of calcium sulfate. Magnesium sulfate and calcium chloride should therefore not be mixed for parenteral administration.

Phosphate containing medicinal products
Mixing calcium salts with carbonates may cause precipitation of calcium carbonates. Carbonate-containing medicinal products and calcium salts should not be mixed for parenteral administration.

Tartrate containing medicinal products
Mixing of calcium salts with tartrates may cause precipitation of calcium tartrate. Tartrate-containing medicinal products and calcium salts should not be mixed for parenteral administration.

6.3 Shelf life

3 years

6.4 Special precautions for storage

No special storage conditions.

6.5 Nature and contents of container

Clear glass ampoules.
Pack sizes: 10x10 ml, 20 x 10 ml, 50 x 10 ml, 100 x 10 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Only for single use, unused product should be discarded.

The product should be visually inspected in regards to particles and miscolouration before administration. Only clear, colourless solution free of particles and precipitations must be used.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Abboxia AB
Box 50
431 21 Mölndal

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

18 December 2025