℞ **Injection of Calcium Gluconate & Calcium Lactobionate**

CALCIGLU
Injection

Composition:
Each ml contains
Calcium Gluconate IP.....50 mg
Calcium Lactobionate USP.....87.5 mg
eq. to elemental Calcium.....9 mg
Water for Injection IP.....q.s.

For IM/IV Use Only

What is calcium gluconate 10% and what is it used for?
Calcium Gluconate 10% is a solution for calcium supplementation.
It is used for calcium supplementation in patients with abnormally low calcium concentration in the blood (hypocalcemia) who exhibit acute symptoms such as decreased skin sensitivity (numbness, itching, burning sensation), spasmodic muscle stiffness (tetany), cramps in the hands and feet, colic, muscle weakness, confusion, possibly leading to seizures and heart symptoms (e.g., irregular heartbeat and even acute heart failure).

When should you not use this medicine or take extra caution?
When should you not use this medicine? You are allergic to any of the ingredients in this medicine.
• if you have excessive calcium in the blood (e.g., in patients with an overactive parathyroid gland (hyperparathyroidism), excess vitamin D in the blood, tumors causing bone loss, impaired kidney function, osteoporosis due to lack of exercise, sarcoidosis, and the milk-alkali syndrome);
• in case of increased excretion of calcium in the urine;
• in case of poisoning with digitalis preparations (a type of heart medication);
• during treatment with digitalis preparations unless you have extremely low calcium levels in the blood with life-threatening symptoms that can only be treated with direct calcium injection;
• The antibiotic ceftriaxone should not be used in premature infants and newborns (< 28 days old) if they are being treated (or are expected to be treated) with calcium-containing products administered intravenously.

When should you take extra caution with this medicine?
Contact your doctor before using this medicine.
If you are taking digitalis preparations on a regular basis and you urgently need a calcium injection (see above), your doctor will carefully monitor your heart function. The monitoring will ensure that deterioration of your heart function, such as severe arrhythmias (irregular heartbeat), can be immediately treated.
Your doctor will carefully consider whether this medicine is suitable for you if you have:
• Calcium deposition in the kidneys (nephrocalcinosis) • Heart diseases • Sarcoidosis
In these cases, you should only receive calcium injections if they are absolutely necessary. This also applies if you are receiving adrenaline (see 'Are you taking any other medicines') or if you are elderly.
Impaired kidney function (renal insufficiency) can be associated with increased calcium levels in the blood and an overactive parathyroid gland. If you have renal insufficiency, you should only receive calcium injections if they are absolutely necessary. However, your calcium and phosphate balance should be monitored.
Your doctor will exercise extra caution if you are being treated with the antibiotic ceftriaxone. Your doctor will not administer this concurrently with calcium gluconate, even through a different infusion line or at a different infusion site.
Calcium should be injected slowly to prevent possible vasodilation or impaired heart function.
Your heart rate or ECG should be monitored when this medicine is injected into a vein (intravenous injection).
During treatment with calcium salts, you will be closely monitored to ensure that your calcium balance (calcium intake versus calcium excretion) is normal and to prevent any calcareous deposits in the tissues. Blood calcium levels and the amounts of calcium excreted in the urine will be monitored, especially when high doses of calcium are injected.
Calcium is insoluble in adipose tissue and can cause inflammatory reactions followed by abscess formation, tissue hardening, and tissue breakdown (necrosis) if accidentally injected into these areas.
If the solution is accidentally injected next to a blood vessel or not deep enough into the muscle, this can result in local tissue irritation, possibly followed by skin peeling or even necrosis (see section 4). Your doctor will ensure that no solution escapes into the tissue around the blood vessels and will carefully monitor the injection site.
High doses of vitamin D should be avoided.
Children and adolescents under 18 years of age
Calcium Gluconate 10% should only be injected into the veins in children (<18 years old), not into the muscle (IM).

Are you taking any other medicines?
In addition to Calcium Gluconate 10%, are you taking any other medicines, or have you recently taken any, or is there a possibility that you will be taking other medicines in the near future? Please inform your doctor.
The effect of heart medications such as digoxin and other digitalis drugs can be increased by calcium, which can lead to digitalis poisoning. Therefore, if you are being treated with digitalis medications, you will only receive an intravenous calcium injection for the treatment of severe, immediately life-threatening symptoms of very low calcium levels in the blood.
Administration of calcium together with adrenaline after heart surgery weakens the effects of adrenaline on the heart and circulation.
Calcium and magnesium inhibit each other's effects.
Calcium can reduce the effect of certain medications used to regulate heart function (calcium antagonists). Administration of certain medications that increase urine formation and urine production (thiazide diuretics) together with calcium can result in exceptionally high calcium levels in the blood (hypercalcemia) because these medications reduce the excretion of calcium through the kidneys.
Administration of calcium simultaneously with ceftriaxone leads to the formation of precipitates.
Pregnancy and breastfeeding: Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Then contact your doctor before using this medicine.
Pregnancy: Calcium crosses the placenta into the fetal bloodstream and reaches higher levels in the fetal blood than in the mother's blood. Calcium will only be administered to pregnant women if the doctor deems it absolutely necessary. The dose must then be carefully calculated, and the calcium levels in the blood must be regularly monitored to avoid high calcium levels in the blood, which could be detrimental to the fetus.
Breastfeeding: Calcium is excreted in breast milk. The doctor will take this into account if calcium is administered to you while breastfeeding
Driving and using machines: This medicine does not affect driving ability and the use of machinery.
How to use this medicine? Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor.
Your doctor will select the recommended dosage and method of administration necessary to increase the calcium concentration in your blood / bring the calcium concentration in your child's blood to a normal level.

Adults: The usual dosage is 10 ml, which is one ampule of Calcium Gluconate 10%. If necessary, the dosage can be repeated. Subsequent dosages will be adjusted based on the actual calcium concentration in your blood.
Use in infants, toddlers, children, and adolescents under 18 years of age: The doctor will decide on the dosage and method of administration depending on the calcium levels in the blood and the severity of the symptoms. In the case of mild symptoms that do not pose an immediate threat to life, the doctor may choose not to administer calcium or to use alternative treatments.
How to use this medicine? Always use this medication exactly as your doctor has told you. If you are unsure about the correct usage, please contact your doctor.
Your doctor will determine the recommended dosage and method of administration necessary to increase the calcium concentration in your blood/bring the calcium concentration in your child's blood to a normal level.
Adults: The usual dosage is 10 ml, which is equivalent to one ampoule of Calcium Gluconate 10% B. Braun. If necessary, the dosage can be repeated. Subsequent dosages will be adjusted based on the actual calcium concentration in your blood.
Elderly patients: Certain disorders that are sometimes associated with advanced age, such as renal impairment and malnutrition, may affect the tolerance for calcium gluconate. In such cases, a lower dosage should be chosen.
Method of use: This medication will be administered to you as a slow injection into a vein or a deep injection into a large muscle. You should be in a lying position during administration, and your heart function should be carefully monitored, particularly during the injection.
Due to the risk of local tissue irritation, injections into a muscle (intramuscular injection) should only be performed when intravenous injection is not feasible. Your doctor will ensure that intramuscular injections are administered deep enough, preferably in the large gluteal muscle.
The intravenous infusion or injection should not be performed too quickly.
Infants, toddlers, children, and adolescents up to 18 years of age: For intravenous administration (in a vein) as a slow injection or slow intravenous infusion (drip infusion), both after dilution.
This medication should not be injected into a muscle or under the skin in children.
If you have used too much of this medication: Symptoms of high blood calcium levels (hypercalcemia) may include loss of appetite, nausea, vomiting, constipation, abdominal pain, increased urine output (polyuria), thirst (polydipsia), dehydration, muscle weakness, kidney stones, drowsiness, confusion, high blood pressure (hypertension), and, in severe cases, irregular heartbeat, cardiac arrest, and loss of consciousness.
Symptoms of high blood calcium levels (hypercalcemia), a chalky taste, hot flashes, and a drop in blood pressure may occur if the intravenous injection is performed too quickly.
Treatment aims to lower the elevated calcium concentration in the blood. Your doctor will decide on the appropriate treatment, which may involve administering fluids

Possible side effects
Like any medication, this medicine can have side effects, although not everyone experiences them.
• The frequency of side effects is expressed as follows:
• Very common: affects more than 1 in 10 users
• Common: affects less than 1 in 10 users
• Uncommon: affects less than 1 in 100 users
• Rare: affects less than 1 in 1,000 users
• Very rare: affects less than 1 in 10,000 users
• Unknown: based on the available data, the frequency cannot be determined
Side effects on the heart, blood circulation, or other bodily functions may occur as symptoms of extremely high calcium levels in the blood due to overdose or rapid injection into the vein. The presence and frequency of such symptoms are directly related to the injection speed and dose administered.
The following side effects can be serious. If you experience any of the following side effects, inform your doctor immediately; they will discontinue the administration of this medicine.
Rare (affects less than 1 in 1,000 users): Severe, and in some cases fatal, side effects have been reported in premature infants and newborns (<28 days) treated intravenously with ceftriaxone and calcium. Autopsy findings have shown precipitation of ceftriaxone with calcium salt in the lungs.
Other side effects include: Unknown (based on the available data, the frequency cannot be determined): Dilatation of blood vessels, Flushing, especially if the injection is administered too rapidly, Feeling unwell or vomiting, Sensation of warmth, Sweating
Muscle injections may be accompanied by pain and redness.
Side effects when the medicine is used improperly: If the injection is not administered deep enough into the muscles, the solution may penetrate the fatty tissue, which could potentially lead to inflammation, tissue hardening, and even tissue necrosis.
Reports of calcium deposition in the surrounding tissue have been observed after solution leakage from a vein. This may cause peeling and necrosis of the skin.
Redness of the skin and a burning sensation or pain at the site of intravenous injection may indicate inadvertent injection outside the blood vessel, which may result in tissue breakdown.
Storage: Store below 30°C, Protected from light. Do not freeze.
Note: Improper storage may deteriorate the product.
Keep the medicine out of reach of children.

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Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A,
Harihar Complex, Bhiwandi, Mumbai - 421302
E-mail: info@americanremedies.in
ICO: American Remedies LLC, DE, USA
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