PACKAGE LEAFLET: Information for the user

GLUKAPRO

Solution for infusion – 1000 mg / 10 ml

(Calcium gluconate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT GLUKAPRO IS AND WHAT IT IS USED FOR

GlukaPro is a solution for infusion to be administered directly into the vein (intravenous infusion) that contains the active ingredient calcium gluconate.

Calcium is an essential element for the proper functioning of the nervous system, the muscles, heart and blood vessels; it is also an essential component of bones.

This medication is indicated for the treatment of calcium deficiency states (hypocalcemia) and, in combination with other medicines, in the treatment of severe allergic reactions (anaphylactic treatment); it is also indicated for the control of increased permeability of small blood vessels in allergic conditions and in case of skin disease characterized by redness and bruising

(nonthrombocytopenic purpura).

2. BEFORE YOU TAKE GLUKAPRO

Do not take GlukaPro if:

- you are hypersensitive to calcium gluconate or to any of the excipients of the solution for infusion (listed in section 6);
- you have diseases or conditions that cause increased levels of calcium in the blood (hypercalcemia), for example, hyperactivity of the parathyroid glands (hyperparathyroidism), high vitamin D levels (hypervitaminosis D), cancer disease with bone calcium depletion (neoplastic disease with bone decalcification);
- you have high levels of calcium in your urine (severe hypercalciuria);
- you have severe kidney problems (severe renal failure);
- you have an altered heartbeat called ventricular fibrillation;
- you are taking cardiac glycosides, medicines for heart disease (see section "Taking other medicines");
- the patient is an infant (up to 28 days of age), GlukaPro (or other calcium solutions) should not be given concurrently with ceftriaxone (an antibiotic), even if separate infusion lines are used. There is a fatal risk of particle formation in the infant's bloodstream.

Take special care with GlukaPro

Talk to your doctor, pharmacist or nurse before being given GlukaPro solution for infusion 1000 mg / 10 ml if you:

- suffer from chronic kidney disease or you are at risk of stone formation in your urinary tract;
- suffer from deposition of calcium in the kidneys (nephrocalcinosis);
- have sarcoidosis (swollen or inflamed patches of tissue, usually affecting the lungs and skin);
- have heart disease;
- have impaired kidney function. This condition can be associated with increased blood calcium levels and overactive parathyroid glands so your doctor will carefully monitor chemicals in your blood and you will receive this medicine only if it is absolutely essential;
- are receiving adrenaline (epinephrine).

This medication should not be mixed in the same infusion set with other incompatible (e.g., ceftriaxone) or total parenteral nutrition solutions containing calcium and phosphate, nor administered separately in succession because serious, even fatal, complications occur due to precipitation of calcium salts insoluble in the body.

Laboratory tests

This medication may result in false negatives for tests of magnesium levels in the blood and urine.

Children

As with other calcium-containing solutions, concomitant treatment with ceftriaxone is contraindicated in infants (up to 28 days of age), even when using separate infusion lines, because of the fatal risk of precipitation of ceftriaxone-calcium salt in the infant's bloodstream (see section "Possible side effects").

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important with the following medicines as they may interact with GlukaPro:

- digoxin (a heart medicine) and other cardiac glycoside medicines may have their effect increased;
- thiazide diuretics, may reduce your body’s ability to eliminate calcium and high levels may occur;
- ceftriaxone (an antibiotic), due to the risk of precipitation, must not be given simultaneously, even via separate infusion lines;
- adrenaline (epinephrine), a medicine used after heart surgery, may have its effect reduced;
- magnesium and calcium may reduce each other’s effects;
- calcium channel blockers (heart medicines), may have their effects reduced.

Pregnancy and breastfeeding

If you are pregnant, suspect or plan to become pregnant or are breastfeeding, ask your doctor for advice before you are given this medicine.

This medicinal product should not be administered during pregnancy and during lactation unless absolutely necessary and in accordance with medical advice.

Calcium is secreted in breast milk. This must be taken into account when prescribing calcium to women during lactation.

Driving and using machines

This medicinal product does not affect the ability to drive vehicles or operate machinery.

3. HOW TO TAKE GLUKAPRO

This medicine will be prepared by a doctor, pharmacist or nurse and will not be mixed or administered at the same time as injections containing ceftriaxone or other incompatible medicines.

This medicine must be administered by trained medical personnel by means of a very slow direct administration into a vein (intravenous infusion) (infusion rate recommended infusion rate of no more than 1.5 ml per minute). It must not be injected via other routes of administration (intramuscular or subcutaneous route) (see section “Take special care with GlukaPro”).

The recommended dose in adults is 500-2000 mg of calcium gluconate (equivalent to 5-20 ml of solution).

Treatment with calcium gluconate is aimed at restoring or maintaining calcium levels in the blood in the blood between 2.25-2.75 mmol/l (or 4.5-5.5 mEq/l). During therapy, therefore, calcium levels in the blood must be monitored very closely during therapy.

Use in children

In children, the recommended dose is 200-500 mg of calcium gluconate (equivalent to 2-5 ml of solution).

In infants, the recommended dose should not exceed 200 mg of calcium gluconate (not more than 2 ml of solution).

Use in the elderly

In the elderly, the dosage of the medicinal product should be reduced according to tolerability which may be affected by advanced age and pre-existing factors and clinical situations.

Preparation of the medicinal product: calcium gluconate for intravenous use may be diluted with solutions of 5% glucose or 0.9% sodium chloride. Dilution in solutions containing bicarbonates, phosphates or sulphates should be avoided. Do not use the medicine if the solution solution is not clear; any precipitate can be redissolved by slight warming in warm water.

If you take more GlukaPro than you should

If you take more GlukaPro than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital, or call the emergency to get an opinion of the risk and advice on the action to be taken.

If you forget to take GlukaPro

If you forget a dose, take the next dose when it is the normal time to take it.
Do not take a double dose to make up for the forgotten dose.
If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects may be serious. If any of the following side effects occur tell your doctor immediately:

Frequency: rare (may affect up to 1 in 1,000 people)

- Severe side effects, in some cases leading to death, have been reported in premature and newborn babies (aged up to 28 days) who had been treated with intravenous ceftriaxone (an antibiotic) and calcium.

Frequency: Not known (cannot be determined from available data)

- slow or irregular heartbeat
- drop in blood pressure (hypotension)
- circulatory collapse (enlarging of blood vessels with a life-threatening drop in blood pressure)
- hot flushes, mainly after the injection has been given too rapidly
- feeling sick (nausea) or being sick (vomiting)
- sensation of heat
- sweating.

Side effects when GlukaPro infusion is used incorrectly or in special situations

- Too rapid injection or infusion may cause cardiovascular side effects, due to high levels of calcium. The presence and frequency of such symptoms depend on the speed of infusion and the given dose.
- It has been reported that following leaking of the solution from a vein into the surrounding tissue (extravasation), calcium deposition in the soft tissue may occur. It may be followed by peeling and destruction of the skin.

If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE GLUKAPRO

Keep out of the reach and sight of children!
Do not use GlukaPro after the expiry date which is stated on the package.
Do not store above 25°C!

6. FURTHER INFORMATION

What GlukaPro solution for infusion contains

The active substance is calcium gluconate. Each ampule of 10 ml contains 1000 mg of calcium gluconate (equal to 950 mg calcium gluconate monohydrate and 36 mg calcium saccharate tetrahydrate). Each litre of solution contains 446 mEq of calcium.
The excipients are: calcium saccharate tetrahydrate, sodium hydroxide, and water for injection.

Content of the pack

Box with 10 ampoules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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This leaflet was formulated in August 2023.