

Package leaflet: Information for the user

Icalziss 340 mmol/L solution for infusion calcium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Icalziss is and what it is used for
2. What you need to know before you use Icalziss
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1. What Icalziss is and what it is used for

Icalziss is a solution for infusion containing calcium chloride dihydrate. It is used for calcium replacement during continuous renal replacement therapies (CRRT) and therapeutic plasma exchange (TPE), either as single treatment or in combination, in adults and children of all ages (above 8kg). This medicine allows to keep calcium levels in the blood in the desired range when citrate anticoagulation treatment is used.

2. What you need to know before you use Icalziss

Do not use Icalziss:

- if you have a high level of calcium in your blood
- if you have a high level of chloride in your blood
- if you have allergy to the active substances or to any of the other ingredients (listed in section 6).
- in newborns that are being treated with ceftriaxone.

Warning and precautions

Talk to your doctor, pharmacist or nurse before using Icalziss.

Patients may experience irregular heartbeat, particularly if they are administered digitalis glycosides after being treated with this medicine. Too much systemic calcium in the heart increases the risk of cardiac syncope, which is a brief loss of patient's consciousness. Patients intoxicated or treated with digitalis glycosides may experience symptoms such as confusion, irregular pulse, and fast heartbeat after the application of calcium containing solutions. It is recommended to administer small amounts of this medicine if intravenous administration of calcium is necessary.

Your doctor will monitor and control the amount of electrolytes and the level of acidity and alkalinity of your blood. Your doctor will correct the levels of calcium and chloride in your blood before starting the treatment.

Throughout the treatment, your doctor may increase or reduce the amount of calcium chloride being administered depending on calcium level in your blood.

If the treatment duration is prolonged, or if it is repetitively applied, your doctor will evaluate the level of hormones your body produce to control calcium levels in your blood and the bone ability to release or reabsorb calcium.

The administration of calcium chloride may increase the risk of renal stones formation.

The administration of calcium salts through the vein can cause escape of blood or fluid into tissue. Your doctor will regularly inspect the site of infusion for signs of clotting. Your doctor will stop the administration of this medicine if clotting is observed.

Risks for complications from too much or too little calcium in the blood are increased in patients suffering from conditions such as nephrocalcinosis, hypercalciuria, cancer, hyperparathyroidism, hypoparathyroidism, rhabdomyolysis, and liver failure.

Moderate reduction on the body temperature to 30-34°C can lead to complications associated to high concentration of calcium in the blood (hypercalcaemia).

Inform your doctor if you are being treated with ceftriaxone.

Use only if the solution is clear and free from visible particles.

Other medicines and Icalziss

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. This is because the concentration of other medicines may be reduced during dialysis treatment. Your doctor will decide if any changes in the dosage of your medicines should be made.

Tell your doctor if you are using medicinal product containing Vitamin D or vitamin D analogues, or other medicinal products containing calcium, calcium chloride or calcium gluconate; as they can increase the risk of a high concentration of calcium in the blood (hypercalcaemia) and can result in a reduced anticoagulation effect.

Interactions are possible with:

- certain medicines containing vitamin D and other vitamin D analogues.
- certain medicines that lower the serum calcium level (calcimimetics, such as etelcalcetide and cinacalcet).
- certain medicines used to increase urine production (thiazide diuretics).

Icalziss is incompatible with inorganic phosphate, carbonates, tetracycline antibiotics, ceftriaxone and others.

Pregnancy and breast-feeding

Pregnancy and breastfeeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

Icalziss should only be used during pregnancy if your doctor considers treatment absolutely necessary.

Breastfeeding is possible if you need treatment with this medicine during that time.

Driving and using machines

Icalziss is not known to affect your ability to drive or use machines.

3. How to use Icalziss

For intravenous use. Icalziss is to be used in hospitals and administered by medical professionals experienced in citrate anticoagulation for specific treatment with CRRT and/or TPE only. The volume used, and therefore the dose of this medicine, will depend on your condition. The dosage will be determined by your doctor.

Instructions for use

Icalziss will be given to you in a hospital. Your doctor will know how to use this medicine.

For instructions for use see the end of this leaflet.

If you are given more Icalziss than you should

As Icalziss will only be given to you by a doctor, it is unlikely that you will be given too little or too much. However, if you think you have been given too much of this medicine, please tell your doctor or nurse.

The signs of an overdose may be symptoms of high calcium levels in your blood e.g. tiredness, tingling, lack of energy, disorientation, overresponsive reflexes, nausea, vomiting, constipation, tendency to develop gastrointestinal ulcers, racing heartbeat, slow heartbeat and irregular heartbeat with a possibility of cardiac arrest, high blood pressure, alterations in electrocardiogram, fainting, passing more urine than normal, thirst, water loss without electrolyte loss, calcium deposits in your kidneys, a chalky taste, hot flushes, widening of the blood vessels with low blood pressure.

In case of very high calcium levels, also called hypercalcaemic crisis, the following signs are present: vomiting, colic, lack of intestinal muscle tone, bowel obstruction, generalised weakness, disturbance of consciousness, initially passing more urine than normal, then often passing less or not passing urine.

If you get any of the above mentioned symptoms please tell your doctor or nurse immediately.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your blood will be regularly monitored by a doctor or nurse in order to find possible side effects. Use Icalziss could cause:

Not known: frequency cannot be estimated from the available data

- too much or too low fluid in your body
- high or low blood calcium levels
- high blood acidity or high blood alkalinity
- electrolyte imbalance (e.g. low blood levels of potassium or phosphate, or excess of chloride in the blood)
- low blood pressure
- low body temperature

The following side effects may occur as a result of the treatment method in general:

- wrong application can cause irritation at the site of infusion, escape of blood or fluid into tissue which can cause burning, gangrene, sloughing of tissue, cellulitis and soft tissue hardening

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Icalziss

Keep this medicine out of the sight and reach of children.

Do not freeze.

As soon as the overwrap is removed, Icalziss must be used within 72 hours. If not used according to Instructions for Use, the in-use storage times and conditions are the responsibility of the user.

Do not use this medicine after the expiry date which is stated on the label and the packaging. The expiry date refers to the last day of that month.

The content must be used immediately after bag opening.

Do not use this medicine if you notice damage to the product or visible particles in the solution.

The solution is for single use only. Any unused solution and damaged container should be discarded.

The solution can be disposed of via wastewater without harming the environment.

6. Contents of the pack and other information

What Icalziss contains

Composition:

Calcium chloride dihydrate	50 g/l
Calcium, Ca ⁺⁺	340 mmol/l
Chloride, Cl ⁻	680 mmol/l

Theoretical osmolality: 1020 mOsm/l

pH ≈ 5.5 - 7.5

The other ingredient is:

Water for injections

What Icalziss looks like and contents of the pack

Icalziss is a clear and colourless solution for infusion packed in a one-compartment bag made of a multilayer film containing Polypropylene (PP), Polyamide (PA) and Polyethylene (PE), with an administration port made of high-density polyethylene (HDPE). The solution is sterile and free from visible particles. Each bag contains 500 ml solution and the bag is overwrapped with a transparent film. Each box contains 20 bags and one package leaflet.

Marketing Authorisation Holder

Vantive Belgium SRL
Boulevard d'Angleterre 2
1420 Braine-l'Alleud
Belgium

Manufacturer

Bieffe Medital S.A.
Ctra de Biescas - Senegüé
22666 Sabiñánigo (Huesca)
Spain

For further information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden: Icalziss
France, Lithuania: Icoziss
Bulgaria: Icalziss (Икалзис)

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The following information is intended for healthcare professionals only:

Do not use unless solution is clear and colourless and the bag and connector are undamaged. The content must be used immediately after opening. For single use only. Any unused solution must be discarded.

Posology

Icalziss should be administered as prescribed by the physician experienced in citrate anticoagulation for specific treatment with CRRT and/or TPE.

This medicine is used as a calcium replacement solution and must be administered through a separate central venous access line or through the return-line of the extracorporeal blood circuit.

Do not add supplementary medication.

Administration rate must be adjusted to maintain systemic ionized calcium levels in the normal physiological range between 1.0 – 1.3 mmol/L to avoid complications associated to hypocalcaemia or hypercalcaemia. Systemic ionized calcium level must not fall below 0.9 mmol/L.

Monitoring of the post-filter blood ionized calcium (iCa), systemic blood iCa, and total blood calcium levels in conjunction with other laboratory and clinical parameters are essential to guide appropriate medicine dosage based on the desired level of anticoagulation during extracorporeal therapies with RCA. Citrate accumulation occurs when the ionized calcium and total calcium ration becomes >2.25 .

Systemic ionized calcium levels should be evaluated at baseline, during the first hour of therapy initiation or dose adjustment until stable, and then at least every 6 hours. Monitoring the systemic total calcium levels every 12 to 24 hours is recommended.

The amount of calcium chloride required to maintain systemic ionized calcium levels within the desired range depends on a number of factors, such as:

- The amount of calcium required to compensate the effects of citrate reaching the systemic circulation and patient's citrate metabolism
- The calcium concentration in the replacement fluid
- Any calcium present in other medications / infusions the patient is taking (e.g., calcium in total parenteral nutrition)
- Any intended change of the baseline systemic calcium concentration
- Any impact on the patient's ionized calcium concentration by other medicinal interventions (e.g., chemotherapy, radiation therapy)
- Other medical conditions that may predispose the patient to hypocalcaemia or hypercalcaemia (e.g., hypoparathyroidism, hyperparathyroidism, malignancy, liver failure, rhabdomyolysis, severe pancreatitis, post-tumour lysis, and toxic shock syndromes)

When determining the appropriate amount of calcium replacement during CRRT, several factors must be considered, such as:

- Prescribed flow rates, especially the effluent flow rate
- Adherence to a standardized protocol or algorithm, which simplifies and facilitates the prescription for calcium replacement and helps decrease errors and variability
- Filter membrane permeability for calcium and calcium-citrate complexes

Adult and adolescent posology:

In RCA-CRRT a typical calcium dose is 1.7mmol per Liter of effluent volume (4-6mmol/h) for adults and adolescents.

A maximum dose of 340 mmol of calcium per day is recommended, which is equivalent to 1 L of Icalziss. This medicine is not intended for chronic use.

Pediatric posology:

The recommended dosage of this medicine for neonates and children (0 to 11 years and above 8 kg) is similar to adults and adolescents. The maximum hourly calcium infusion rate to body weight ratio is 0.3 mmol/h/kg, which is equivalent to a maximum hourly volume infusion rate of 0.88 ml/h/kg. Due to the generally lower prescribed effluent flows in children, correspondingly lower absolute flows of this medicine will result.

The weight limit of >8 kg in the indication is not due to the safety or efficacy characteristics of the medicinal product but is based on the characteristics of the monitoring devices offered by the marketing authorisation holder.

Method of administration

Adjust or stop calcium infusion according to physician's prescription when citrate anticoagulation is stopped.

Infuse only with an extracorporeal blood purification device intended for the infusion of calcium chloride solution and includes an appropriate balance of flow volumes.

Infuse only into the extracorporeal circuit or, if recommended in the instructions for use of the extracorporeal blood purification device, via a separate central venous access. Icalziss is not intended for intramuscular or subcutaneous use.

The instructions for use from the manufacturer of the extracorporeal blood purification device, from the manufacturer of the extracorporeal circuit set and the intravenous line must be followed.

Overdose

Rapid or excessive administration of this medicine may lead to hypercalcaemia (total plasma concentration >3 mmol/L, ionized calcium > 1.3 mmol/L, respectively), which must be corrected as medically appropriate.

Immediately stop or reduce the administration of this medicine if signs or symptoms of hypercalcaemia are noticed. In cases of severely elevated calcium levels, an urgent reduction of calcium levels must be undertaken. If adequate renal function is maintained, a forced diuresis with concomitant infusion of normal sodium chloride solution (9 mg/mL NaCl) should be considered with strict monitoring of fluid balance and plasma electrolyte concentrations. In patients with renal impairment, dialysis with calcium-free dialysate may be considered.

Signs and symptoms of hypercalcaemia include:

- Nervous system disorders, e.g., lethargy, disorientation, hyporeflexia
- Cardiac disorders, e.g., tachycardia and tendency to develop cardiac arrhythmia, hypertension, changes in the electrocardiogram (shortening of QT-interval)
- Gastrointestinal disorders, e.g., nausea, vomiting, constipation, tendency to develop ulcers
- Renal and urinary disorders, e.g., increased diuresis, thirst, aquaresis, renal deposition of calcium salts
- General disorders, e.g., fatigue.

Rapid administration of calcium salts may also lead to chalky taste, tingling, hot flushes, peripheral vasodilation with hypotension, bradycardia, syncope and arrhythmia with a possibility of cardiac arrest.

Preparation and/or handling

The solution can be disposed of via wastewater without harming the environment.

Do not freeze.

The following instructions for use shall be followed:

Aseptic technique should be used throughout the handling and administration to the patient.

This medicine should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear and colorless, and the seal is intact. In case of damage, the container should be discarded.

Remove the overwrap from the bag immediately before use. As soon as the overwrap is removed, this medicine must be used within 72 hours. Press bag firmly to test for any leakage. If leakage is discovered, discard the solution immediately since sterility can no longer be assured. The solution should be used immediately after bag opening to avoid microbiological contamination.

Remove plastic protector from outlet port at bottom of container. Grip the small wing on the neck of the port with one hand. Grip the large wing on the cap with the other hand and twist. The cap will pop off.

Introduce the spike through the rubber septum. Refer to the directions of the set for connection. Verify that the fluid is flowing freely.

Do not reconnect partially used containers. The solution is for single use only. Discard any unused portion. If not used according to Instructions for Use, the in-use storage times and conditions are the responsibility of the user.