Calrecia®

Package leaflet: Information for the user

Calrecia®
100 mmol/l, solution for infusion
calcium chloride dihydrate

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What is in this leaflet

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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

1. What Calrecia® is and what it is used for

Calrecia® is a solution for infusion which contains the active substance calcium chloride dihydrate. This medicine is intended to be used in adults and children during continous renal replacement therapies (CRRT), sustained low efficiency (daily) dialysis (SLEDD) and therapeutic plasma exchange (TPE) to keep calcium levels in the blood in the desired range.

2. What you need to know before you use Calrecia®

Do not use Calrecia®

- if you have a high level of calcium in your blood
- if you have a high level of chloride in your blood.

Warnings and precautions

Talk to your doctor before using Calrecia®.

Check with your doctor before you are given Calrecia® if:

- you are treated with medicines used to treat heart problems (e.g. digitalis glycosides)
- you suffer from additional diseases affecting calcium metabolism and calcium excretion such as deposition of calcium salts in the kidneys, increased calcium excretion with the urine and overdose of vitamin D.

Your doctor will:

- check the bag and the solution before use
- check the site of Calrecia® infusion into the blood tubing regularly for blood clots
- ensure that the calcium level is correct and closely monitored during your treatment
- monitor parathyroid hormone levels and other parameters of bone metabolism
- control the electrolyte and acid-base balance regularly.

Other medicines and Calrecia®

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Interactions are possible with:

- certain medicines used to increase urine production (thiazide diuretics)
- certain medicines used to treat heart problems (digitalis glycosides).
- infusions containing medicines incompatible with calcium, such as some antibiotics (e.g. tetracyclines, ceftriaxone) and specific salts (e.g. inorganic phosphate, carbonates).

Pregnancy and breast-feeding

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 starting treatment with this medicine.

There are not enough data from the use of Calrecia® in pregnant women. Calrecia® should only be used during pregnancy if your doctor considers treatment absolutely necessary.

Breastfeeding is possible if you need treatment with Calrecia® during that time.

3. How to use Calrecia®

Calrecia® will be given in a hospital or clinic. The dosage will be determined by your doctor.

If you use more Calrecia® than you should

As Calrecia® 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 following information is intended for healthcare professionals only:

1000 ml solution contains:

calcium chloride dihydrate	14.7 g
Ca^{2+}	100 mmol
Cl^-	200 mmol
Theoretical osmolarity:	300 mOsm/l
pH:	5.0 – 7.0

Do not use unless solution is clear and colourless and the bag and connector are undamaged. For single use only. Any unused solution must be discarded.

Posology

Dosing of Calrecia® needs to be controlled by regularly measuring the systemic ionised calcium. Based on these controls, adjustments of the flow of Calrecia® need to be made in order to reach the targeted range of systemic ionised calcium. A maximum dose of 3 l/d is recommended and no chronic use is intended.
For details please refer to the Summary of Product Characteristics.

Method of administration

- Infusion only by a pump of the extracorporeal blood purification device, which is intended by its manufacturer for infusion of a 100 mmol/l calcium chloride solution and comprises an appropriate balancing of fluid volumes.
- Infusion only into the extracorporeal blood circuit or, if advised by the instruction for use of the extracorporeal blood purification device, via a separate central venous access. Calrecia® is not intended for intramuscular or subcutaneous use.
- Handling instructions of the manufacturer of the used extracorporeal blood purification device and of the tubing line must be adhered to.

The solution is not intended to be used for the addition of any drugs and not intended to be used for peripheral intravenous infusion.

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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 heart beat, 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.

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

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

The following side effects may occur when Calrecia® is used:

- 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
- high blood calcium levels due to administration of too much of this medicine.

The exact frequency of such events is not known (cannot be estimated from the available data).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

For United Kingdom:
Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

For Malta:
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

For Ireland:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971, Fax: +353 1 6762517
Website: www.hpra.ie, e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calrecia®

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

Do not refrigerate or freeze.

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

The content must be used immediately after opening.

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

6. Contents of the pack and other information

What Calrecia® contains

- The active substance is calcium chloride dihydrate. 1000 ml of solution contain 14.7 g calcium chloride dihydrate corresponding to 100 mmol calcium and 200 mmol chloride.
- The other ingredient is water for injections.

What Calrecia® looks like and contents of the pack

Calrecia® is provided in a bag with 1500 ml ready-to-use solution.

The solution is clear and colourless and free from visible particles.

Each bag is equipped with a connective tubing and a connector and is covered by a protective foil.

Pack sizes:
8 bags of 1500 ml

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Manufacturer
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Handling

The following points prior to the use of the solution bag have to be considered:

1. Separate the two bags at the peal seam.
2. Remove the overwrap only immediately before using the solution. Check the solution bag (label, expiry date, clearness of the solution, bag and overwrap not damaged). Plastic containers may occasionally be damaged during transport from the manufacturer to the dialysis clinic or hospital clinic or within the clinic itself. This can lead to contamination and the growth of bacteria or a fungus in the solution. Therefore careful inspection of the bag and the solution before use is essential. Particular attention should be paid to even the slightest damage to the closure of the bag, the welding seams and the corners of the bag. The solution should only be used if colourless and clear and if the bag and connector are undamaged and intact.
3. Put the bag on the dedicated attachment by its hanger hole.
4. For connection remove the protection cap from the connector. The connector only fits to its counterpart to prevent misconnection. Do not touch the unprotected part especially do not touch on top of the connector. The inner part of the connector is sterile and is not intended to be further treated with chemical disinfectants. Put together the connector with the appropriate counterpart and press together until you can turn it clockwise against the resistance to the stop point. You may hear a “click” sound when the connection is fixed.
5. Proceed with the further steps as indicated in the treatment description.

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