Prescribing Information

Calrecia 100mmol/l, solution for infusion

(Calcium Chloride)

please refer to the Summary of Product Characteristics for detailed information

Presentation: Solution bag with 1500ml ready-to-use solution.
Indications: Calrecia is used for calcium substitution in continuous renal replacement therapies (CRRT), sustained low efficiency (daily) dialysis (SLEDD) and therapeutic plasma exchange (TPE) using citrate for anticoagulation. Calrecia is indicated in adults and children.
Posology and method of administration: Application of Calrecia should take place only based on the prescription of a physician familiar with citrate anticoagulation in the specific mode of CRRT, SLEDD and TPE. ***Adults;*** Calrecia is applied in an amount adequate to keep the systemic ionised Calcium concentration in the desired range. If not otherwise prescribed, the normal range for systemic ionised calcium should be targeted. The target range must not be below 0.9 mmol/l systemic ionised calcium. 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. ***Paediatric population;*** The posology of Calrecia in children is the same as in adults. Due to the generally lower prescribed effluent flows in children, correspondingly lower absolute flows of Calrecia will result. 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.
Contraindications: Hypercalcaemia, Hyperchloremia
Warnings and precautions: Calcium chloride infusion should be used with caution in patients treated with Digitalis-Glycosides. In patients considered at risk to develop cardiac arrhythmia, continuous monitoring of the electrocardiogram should be considered during citrate anticoagulation and calcium infusion. Comorbidities affecting calcium metabolism and calcium excretion such as but not limited to nephrocalcinosis, hypercalciuria and overdose of vitamin D should carefully be considered when prescribing Calrecia. Dose adaptations might be required and blood calcium levels should be closely monitored. Pre-existing hypercalcaemia should be considered by reducing initial calcium infusion rate and close monitoring of blood calcium levels. Pre-existing hypocalcaemia should be corrected prior to starting citrate anticoagulation. Pre-existing hyperchloremia might be corrected by adequate dialysis conditions; alternatively, adjusted application of chloride-poor infusion solutions can be considered.
Interactions with other medicinal products: Additional applications of calcium due to other infusion solutions or medicinal products need to be considered for dosing. In case Calrecia is applied not via the extracorporeal circuit but via a separate central venous catheter, the respective catheter lumen must not be used for any other infusion in parallel. Of note, calcium chloride solution has been demonstrated to be incompatible with various other solutions containing, e.g. inorganic phosphate, carbonates, tetracycline antibiotics, ceftriaxone and others. Patients treated with Digitalis glycosides may show signs of Digitalis overdose after application of calcium containing solutions. Thiazide diuretics decrease urinary calcium excretion. Caution is therefore required if such drugs are administered with both calcium chloride and other calcium-containing preparations.
Fertility, pregnancy and lactation: *Pregnancy*; There are no or limited amount of data from the use of calcium chloride in pregnant women. Calrecia is not recommended during pregnancy unless the clinical condition of the woman requires CRRT, SLEDD or TPE. *Breastfeeding;* Calcium is excreted in human milk, but at therapeutic doses of calcium chloride no effects on the breastfed newborns/ infants are anticipated. Calrecia can be used during breast-feeding unless no other concern arises from the clinical condition of the mother. *Fertility; No human data on the effect of calcium chloride on fertility are available.*
Undesirable effects: Hypothermia, Hyper- or hypohydration, Hypercalcaemia, Hypocalcaemia due to underdosing, Metabolic acidosis or alkalosis, Other electrolyte disturbances (e.g. hypokalaemia, hypophosphataemia), Hypotension **(*please refer to the Summary of Product Characteristics for detailed information*)**
Overdose: Rapid or excessive administration of calcium salts may lead to hypercalcaemia (total plasma concentration >3 mmol/l, ionised calcium > 1.2 mmol/l, respectively). Too rapid injection of calcium salts may also lead to the signs and symptoms of hypercalcaemia as well as chalky taste, tingling, hot flushes, nausea, vomiting and peripheral vasodilation with hypotension, bradycardia, syncope and arrhythmia with a possibility of cardiac arrest.
Legal Category: POM
NHS list price each: £50 excluding VAT
Marketing authorisation number: PL13689/0026 (**UK**)
Marketing authorisation holder: Fresenius Medical Care Deutschland GmbH, Else-Kröner-Straße 1, 61352 Bad Homburg v.d.H., Germany
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellowcard in the Google Play or Apple App Store. Adverse events should also be reported to Fresenius Medical Care UK Ltd on 0800 001 4499