DESCRIPTION

10% calcium chloride injection is a sterile, nonpyrogenic, hypotonic solution. Each mL contains 100 mg (1.4 mEq/mL) of calcium chloride, dihydrate (1.4 mEq each of Ca++ and Cl−) in water for injection. It is provided in a 10 mL single-dose vial to facilitate prompt intravenous injection. The solution contains no bacteriostatic, antimicrobial agent or added buffer and is intended for use only as a single-dose injection. The pH of 10% calcium chloride injection is 6.3 (5.5 to 7.5) when diluted with water for injection to make a 5% solution. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. The osmolar concentration is 2.54 mOsm/mL (calc.); 10% calcium chloride injection is oxygen sensitive.

Calcium chloride dihydrate is chemically designated CaCl₂·2H₂O (dihydrate) and is described as white, odorless fragments or granules freely soluble in water.

CLINICAL PHARMACOLOGY

Calcium is the fifth most abundant element in the body and the major fraction is in the bony structure. Calcium plays important physiological roles, many of which are poorly understood. It is essential for the functional integrity of the nervous and muscular systems. It is necessary for normal cardiac function and is one of the factors that operates in the mechanisms involved in the coagulation of blood.

Calcium chloride in water dissociates to provide calcium (Ca++) and chloride (Cl−) ions. They are normal constituents of the body fluids and are dependent on various physiological mechanisms for maintenance of balance between intake and output. Approximately 80% of body calcium is excreted in the feces as insoluble salts; urinary excretion accounts for the remaining 20%.

INDICATIONS AND USAGE

10% calcium chloride injection is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels.

CONTRAINDICATIONS

Calcium chloride is contraindicated for cardiac resuscitation in the presence of ventricular fibrillation or in patients with the risk of existing digitoxic toxicity.

Calcium chloride is not recommended in the treatment of astyolic and electromechanical dissociation.

WARNINGS

10% calcium chloride injection is irritating to veins and must not be injected into tissues, since severe necrosis and sloughing may occur. Great care should be taken to avoid extravasation or accidental injection into peripheral tissues.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

DOSEAGE AND ADMINISTRATION

10% calcium chloride injection is administered only by slow intravenous injection (not to exceed 1 mL/min), preferably in a central deep vein. The usual precautions for intravenous administration, whenever solution and container permit, should be observed. The injection must be warmed to body temperature. The injection should be halted if the patient complains of any discomfort; it may be resumed when symptoms disappear.

The usual adult dosage in hypocalcemic disorders ranges from 200 mg to 1 g (2 to 10 mL) at intervals of 1 to 2 days depending on the response of the patient and/or results of serum ionized calcium determinations. Repeated injections may be required because of rapid extracellular administration.

Calcium chloride is not recommended in the treatment of magnesium intoxication due to overdosage of magnesium sulfate, and to combat the deleterious effects of hyperkalemia as measured by electrocardiogram (ECG), pending correction of the increased potassium level in the extracellular fluid. However, adequate well-controlled, randomized clinical studies have not been done to support these indications.

To report SUSPECTED ADVERSE REACTIONS, contact American Regent, Inc. at 1-800-734-9230 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

AMERICAN REGENT

SHIRLEY, NY 11967

Revised: July 2017

IN6710

Customer:

MPH USA Design Group

Colours Used:

Item Code:

IN6710

Description:

Epinastine HCI/Ophthalmic Solution, 0.05

OC/EPP Number:

EP9D8509

Size (Flat/Folded):

10.00" x 11.00" 1.250" x 1.250"

Market:

USA

Language:

English

Barcode:

UPC-A 36517671010

PharmaCode:

CJE

Proof By:

CJE

Date:

18/09/2017

Min. Point Size:

8 pt

Approval Signature:

X

Warning:

We cannot accept responsibility for any errors in this proof after approval. While we take extreme care at all times to ensure accuracy to our client’s brief, the final responsibility must be taken by our client.

IF YOU SIGN THIS PROOF YOU ARE SIGNIFYING FULL APPROVAL OF DESIGN AND TEXT.