

10% Calcium Chloride Injection, USP



Benefits and Features

- Ready-to-administer prefilled syringe
- Not made with natural rubber latex, DEHP, or PVC
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- Luer Lock syringe compatible with Luer-Activated IV Systems
- AP rated
- Bar Coded
- No preservatives

SKU(s) in Product Family

UoS† NDC	Product #	Fill Volume	Concentration (mg/mL)	Content	Unit / BX	Bar Coded
64253-0900-36	MCC-0030	10 mL	100 mg/mL	1000 mg/10 mL	60	✓
64253-0900-91	90091	10 mL	100 mg/mL	1000 mg/10 mL	10	✓

Wholesalers Item Number

UoS† NDC	AmerisourceBergen	Cardinal Health	McKesson Drug	McKesson MedSurg	Morris & Dickson
64253-0900-36	10229819	5566435	2315224	1158369	781773
64253-0900-91	10257314	5716816	1569037	1179481	021196

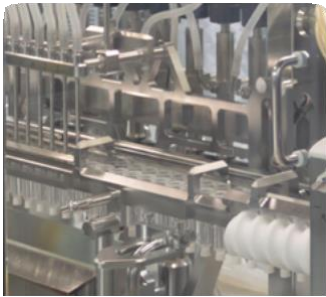
To learn more about Medefil's 10% Calcium Chloride Injection, USP please visit our website at www.medefilinc.com, call (630) 682-4600, or via email at: info@medefilinc.com

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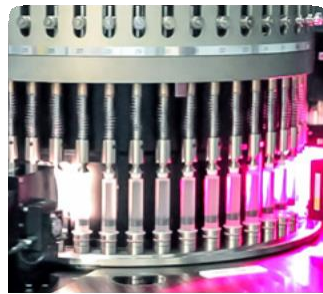
About Medefil

Medefil is growing as a fully integrated specialty pharmaceutical company. At Medefil our goal is to develop and manufacture injectable products where quality and supply reliability are crucial, and safety and ease-of use are of utmost importance. Medefil has a state-of-the-art scientific research infrastructure and high-quality manufacturing capabilities leading to effective execution of development and product supply.

State-of-the-art Manufacturing



Filling



Inspection



Labeling



Packaging

Important Safety Information

WARNINGS:

10% Calcium Chloride Injection, USP 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 perivascular 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.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS:

Do not administer solution if clear and seal is intact. Discard unused portion.

Because of its additive effect, calcium should be administered very cautiously to a patient who is digitalized or who is taking effective doses of digitalis or digitalis-like preparations.

Injections should be made slowly through a small needle into a large vein to minimize venous irritation and avoid undesirable reactions.

It is particularly important to prevent a high concentration of calcium from reaching the heart because of the danger of cardiac syncope.

For Single Use Only:

Reuse of single-use products contains a potential risk to the user. Contamination of the product and/or limited functionality of the device may lead to injury, illness or death. Discard unused portion.

ADVERSE REACTIONS:

Rapid injection may cause the patient to complain of tingling sensations, a calcium taste, a sense of oppression or “heat wave”.

Injections of calcium chloride are accompanied by peripheral vasodilatation as well as a local “burning” sensation and there may be a moderate fall in blood pressure.

Should perivascular infiltration occur, I.V. administration at that site should be discontinued at once. Local infiltration of the affected area with 1% procaine hydrochloride, to which hyaluronidase may be added, will often reduce venospasm and dilute the calcium remaining in the tissues locally. Local application of heat may also be helpful.

To report SUSPECTED ADVERSE REACTIONS, contact Medefil, Inc. at 1-630-682-4600 or www.medefilinc.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For complete prescribing information, refer to the package insert.



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