# CALCIUM CHLORIDE- calcium chloride injection injection, solution
# Medefil, Inc.

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**
**These highlights do not include all the information needed to use 10% CALCIUM CHLORIDE INJECTION, USP safely and effectively. See full prescribing information for 10% CALCIUM CHLORIDE INJECTION, USP.**
**10% CALCIUM CHLORIDE INJECTION, USP for Intravenous Injection**
**Initial U.S. Approval: 2019**

## INDICATIONS AND USAGE

(3)
10% Calcium Chloride Injection, USP is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels. (3)

## CONTRAINDICATIONS

Calcium chloride is contraindicated for cardiac resuscitation in the presence of ventricular fibrillation or in patients with the risk of existing digitalis toxicity. (4)
Calcium chloride is not recommended in the treatment of asystole and electromechanical dissociation. (4)

## 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.

## DOSAGE AND ADMINISTRATION

10% Calcium Chloride Injection, USP is administered only by slow intravenous injection (not to exceed 1 mL/min), preferably in a central or deep vein. (14)
The usual precautions for intravenous therapy should be observed. If time permits, the solution should be warmed to body temperature. The injection should be halted if the patient complains of any discomfort; it may be resumed when symptoms disappear. Following injection, the patient should remain recumbent for a short time. (14)
The usual adult dosage in hypocalcemic disorders ranges from 200 mg to 1 g (2 to 10 mL) at intervals of 1 to 3 days depending on the response of the patient and/or results of serum ionized calcium determinations. Repeated injections may be required because of rapid excretion of calcium. (14)
The pediatric dosage in hypocalcemic disorders ranges from 2.7 to 5.0 mg/kg hydrated calcium chloride (or 0.136 to 0.252 mEq elemental calcium per kg, or 0.027 to 0.05 mL of 10% Calcium Chloride Injection per kg). No data from clinical trials is available about repeated dosages, though textbook references recommend repeat dosages q 4 to 6 hours. (14)
Caution: 10% Calcium Chloride Injection consists of 1 gram of calcium chloride in a 10 mL syringe, or 100 mg/mL. This concentration represents 27 mg or 1.4 mEq of elemental calcium per mL. Thus, one 10 mL syringe provides 270 mg of elemental calcium. The dosage recommendation in various references is given either as amount of calcium chloride or amount of elemental calcium, and often it is not specified. Ionized calcium concentrations should be measured, to assist in dosage adjustment. (14)
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS. (14)
To prevent needle-stick injuries, needles should not be recapped, purposely bent or broken by hand. (14)

**Revised: 9/2020**

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## FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

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## FULL PRESCRIBING INFORMATION

10% Calcium Chloride Injection, USP is a sterile, nonpyrogenic, hypertonic 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 Unit of Use Syringe to facilitate prompt intravenous injection. The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended for use only as a single-dose injection. The pH of 10% Calcium Chloride Injection, USP is 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 2.04 mOsmol/mL (calc.). 10% Calcium Chloride Injection, USP is oxygen sensitive.

Calcium Chloride, USP dihydrate is chemically designated $CaCl_2 \cdot 2H_2O$ (dihydrate) and is described as white, odorless fragments or granules freely soluble in water.

The plastic syringe is molded from a specially formulated polypropylene. Water permeates from inside the container at an extremely slow rate which will have an insignificant effect on solution concentration over the expected shelf life. Solutions in contact with the plastic container may leach our certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the syringe material.

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 operate 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%.

10% Calcium Chloride Injection, USP is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels.

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.

Do not administer unless solution is 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.

Studies with solutions in polypropylene syringes have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Safety and effectiveness are based on similar clinical conditions in children and adults.

Animal reproduction studies have not been conducted with calcium chloride. It also is not known whether calcium chloride can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Calcium chloride should be given to a pregnant woman only if clearly needed.

An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

None known.

Too rapid injection may produce lowering of blood pressure and cardiac syncope. Persistent hypercalcemia from overdosage of calcium is unlikely because of rapid excretion. In the event of untoward effects from excessive calcium administration, the drug should be discontinued promptly, the patient re-evaluated and appropriate countermeasures instituted, if necessary. See PRECAUTIONS and ADVERSE REACTIONS.

10% Cacliumn Chloride Injection, USP is supplied omn single-dose containers as follows:

| **Unit of Sale** | **Container** | **Total Strength / Total Volume (Concentration)** | **Each** | **Needle** |
|---|---|---|---|---|
| **NDC 64253-900-91**<br>10 mL Single-dose prefilled syringes, individually pouched, in a carton of 10s | Plastic Syringe | 1000 mg/10 mL (100 mg/mL) | NDC 64253-900-30<br>10 mL fill in 12 mL Syringe<br>Single-dose prefilled syringes, individually pouched | None |
| | | | NDC 64253-900-30 | |

| | | | | |
|---|---|---|---|---|
| **NDC 64253-900-36**<br>10 mL Single-dose prefilled syringes, individually pouched, in a carton of 60s | Plastic Syringe | 1000 mg/10 mL (100 mg/mL) | 10 mL fill in 12 mL Syringe<br>Single-dose prefilled syringes, individually pouched | None |

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]. Do not freeze.

Medical literature also refers to the administration of calcium chloride 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.

# 10% Calcium Chloride Injection, USP

## 1000 mg/10 mL (100 mg/mL)

Represents 27 mg (1.4 mEq) $Ca^{++}$/mL.

**Plastic Syringe**

**A HYPERTONIC SOLUTION IN A 10 ML UNIT OF USE SYRINGE FOR PROMPT INTRAVENOUS INJECTION.**

**CAUTION: This solution must not be injected intramuscularly or subcutaneously.**

**Administer only by slow injection (not to exceed 1 mL/minute)**

**Rx Only**

### DESCRIPTION

10% Calcium Chloride Injection, USP is a sterile, nonpyrogenic, hypertonic 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 Unit of Use Syringe to facilitate prompt intravenous injection. The solution contains no bacteriostat, antimicrobial agent or added buffer and is intended for use only as a single-dose injection. The pH of 10% Calcium Chloride Injection, USP is 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 2.04 mOsmol/mL (calc.). 10% Calcium Chloride Injection, USP is oxygen sensitive.

Calcium Chloride, USP dihydrate is chemically designated $CaCl_2 \cdot 2H_2O$ (dihydrate) and is described as white, odorless fragments or granules freely soluble in water.

The plastic syringe is molded from a specially formulated polypropylene. Water permeates from inside the container at an extremely slow rate which will have an insignificant effect on solution concentration over the expected shelf life. Solutions in contact with the plastic container may leach our certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the syringe material.

### 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, USP 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 digitalis toxicity.

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

### 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 unless solution is 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.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:**

Studies with solutions in polypropylene syringes have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

**Pediatric Use:**

Safety and effectiveness are based on similar clinical conditions in children and adults.

**Pregnancy Category C:**

Animal reproduction studies have not been conducted with calcium chloride. It also is not known whether calcium chloride can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Calcium chloride should be given to a pregnant woman only if clearly needed.

**Geriatric Use:**

An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

### 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.

**DRUG ABUSE AND DEPENDENCE**

None known.

**OVERDOSAGE**

Too rapid injection may produce lowering of blood pressure and cardiac syncope. Persistent hypercalcemia from overdosage of calcium is unlikely because of rapid excretion. In the event of untoward effects from excessive calcium administration, the drug should be discontinued promptly, the patient re-evaluated and appropriate countermeasures instituted, if necessary. See ***PRECAUTIONS*** and ***ADVERSE REACTIONS***.

**DOSAGE AND ADMINISTRATION**

10% Calcium Chloride Injection, USP is administered only by *slow* intravenous injection (not to exceed 1 mL/min), *preferably in a central or deep vein.*

The usual precautions for intravenous therapy should be observed. If time permits, the solution should be warmed to body temperature. The injection should be halted if the patient complains of any discomfort; it may be resumed when symptoms disappear. Following injection, the patient should remain recumbent for a short time.

The usual adult dosage in hypocalcemic disorders ranges from 200 mg to 1 g (2 to 10 mL) at intervals of 1 to 3 days depending on the response of the patient and/or results of serum ionized calcium determinations. Repeated injections may be required because of rapid excretion of calcium.

The pediatric dosage in hypocalcemic disorders ranges from 2.7 to 5.0 mg/kg hydrated calcium chloride (or 0.136 to 0.252 mEq elemental calcium per kg, or 0.027 to 0.05 mL of 10% Calcium Chloride Injection per kg). No data from clinical trials is available about repeated dosages, though textbook references recommend repeat dosages q 4 to 6 hours.

*Caution:* 10% Calcium Chloride Injection consists of 1 gram of calcium chloride in a 10 mL syringe, or 100 mg/mL. This concentration represents 27 mg or 1.4 mEq of elemental calcium per mL. Thus, one 10 mL syringe provides 270 mg of elemental calcium. The dosage recommendation in various references is given either as amount of calcium chloride or amount of elemental calcium, and often it is not specified. Ionized calcium concentrations should be measured, to assist in dosage adjustment.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See ***PRECAUTIONS***.

To prevent needle-stick injuries, needles should not be recapped, purposely bent or broken by hand.

**HOW SUPPLIED**

10% Calcium Chloride Injection, USP is supplied in single-dose containers as follows:

| Unit of Sale | Container | Total Strength/ Total Volume (Concentration) | Each | Needle |
|---|---|---|---|---|
| **NDC 64253-900-01**<br><br>10 mL Single-dose prefilled syringes, individually pouched, in a carton of 10s. | Plastic Syringe | 1 g/10 mL (100 mg/mL) | NDC 64253-900-30<br>10 mL fill in 12 mL Syringe<br>Single-dose prefilled syringes, individually pouched. | None |
| **NDC 64253-900-36**<br><br>10 mL Single-dose prefilled syringes, individually pouched, in a carton of 60s. | Plastic Syringe | 1 g/10 mL (100 mg/mL) | NDC 64253-900-30<br>10 mL fill in 12 mL Syringe<br>Single-dose prefilled syringes, individually pouched. | None |

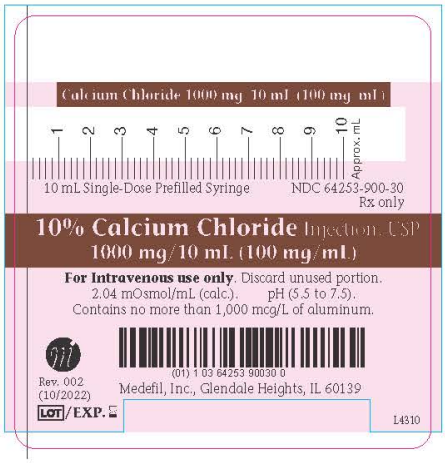
Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Do not freeze.

**CLINICAL STUDIES**

Medical literature also refers to the administration of calcium chloride 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.

Medefil, Inc.
Glendale Heights, IL 60139

L4313 Rev.001, 08/2020


Calcium Chloride 1000 mg/10 mL (100 mg/mL)
1 2 3 4 5 6 7 8 9 10
Approx. mL
10 mL Single-Dose Prefilled Syringe
NDC 64253-900-30
Rx only
10% Calcium Chloride Injection, USP
1000 mg/10 mL (100 mg/mL)
For Intravenous use only. Discard unused portion.
2.04 mOsmol/mL (calc.). pH (5.5 to 7.5).
Contains no more than 1,000 mcg/L of aluminum.
(01) 1 03 64253 90030 0
Rev. 002
(10/2022)
Medefil, Inc., Glendale Heights, IL 60139
LOT/EXP.
L4310

**60s x 10 mL** individually pouched, Single-Dose Prefilled Syringes NDC 64253-900-36
**Rx Only**

# 10% Calcium Chloride Injection, USP

1000 mg/10 mL (100 mg/mL)

**For Intravenous use only**

**Discard Unused Portion** **Single-dose syringe**

Administer by slow intravenous injection only (not to exceed 1 mL/minute)
**Usual Dosage:** See insert. Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature.]

Each mL contains calcium chloride, dihydrate 100 mg. 27 mg (1.4 mEq) Ca++/mL. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH (5.5 to 7.5). 2.04 mOsmol/mL (calc.).

Contains no more than 1000 mcg/L of aluminum. Medication and fluid path are sterile and nonpyrogenic if protective cover is undisturbed and package is intact.

Medefil, Inc.
Glendale Heights, IL 60139

(01) 3 03 64253 90036 6

L4311 Rev. 001 (10/2022)


10 x 10 mL Individually pouched, Single-dose Prefilled Syringes
NDC 64253-900-91
Rx Only
10% Calcium Chloride Injection, USP
1000 mg/10 mL (100 mg/mL)
27 mg (1.4 mEq) Ca++/mL
For Intravenous use only
Single-dose Syringe
Discard Unused Portion
LOT
EXP.
Medefil®
10% Calcium Chloride Injection, USP
Each mL contains calcium chloride, dihydrate 100 mg, 27 mg (1.4 mEq) Ca++/mL. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH (5.5 to 7.0). 2.04 mOsm/mL (calc.).
Contains no more than 1000 mcg/L of aluminum. Medication and fluid path are sterile and nonpyrogenic if protective cover is undisturbed and package is intact.
Pull tab to OPEN
10% Calcium Chloride Injection, USP
1000 mg/10 mL (100 mg/mL)
27 mg (1.4 mEq) Ca++/mL
GLENDALE HEIGHTS, IL 60139
Administer by slow intravenous injection only (not to exceed 1 mL/minute).
Usual Dosage: See insert.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).
[See USP Controlled Room Temperature.]
Medefil, Inc., Glendale Heights, IL 60139

**60 X 10 mL** Individually pouched, Single-dose Prefilled Syringes NDC 64253-900-36
Rx Only

## 10% Calcium Chloride Injection, USP

**1000 mg/10 mL (100 mg/mL)** **27 mg (1.4 mEq) Ca++/mL**

P3025
REV. 002

MEDEFIL®

GLENDALE HEIGHTS, IL 60139

LOT

EXP.

P3025
REV. 002

**60 X 10 mL** Individually pouched, Single-dose Prefilled Syringes NDC 64253-900-36
Rx Only

## 10% Calcium Chloride Injection, USP

**1000 mg/10 mL (100 mg/mL)** **27 mg (1.4 mEq) Ca++/mL**

◆ TEAR TO OPEN ◆

**60 X 10 mL** Individually pouched, Single-dose Prefilled Syringes NDC 64253-900-36
Rx Only

## 10% Calcium Chloride Injection, USP

**1000 mg/10 mL (100 mg/mL)** **27 mg (1.4 mEq) Ca++/mL**

◆ TEAR TO OPEN ◆

**60 X 10 mL** Individually pouched, Single-dose Prefilled Syringes
NDC 64253-900-36
Rx Only

## 10% Calcium Chloride Injection, USP

**1000 mg/10 mL (100 mg/mL)** **27 mg (1.4 mEq) Ca++/mL**

1.8 mm VOID TYPE

PEEL OFF

10 mL

NDC 64253-900-30

Rx only

# 10% Calcium Chloride Injection, USP

1000 mg/10 mL (100 mg/mL)

(01)10364253900300

**Single-dose syringe**

**For intravenous use only**

Each mL contains calcium chloride, dihydrate 100 mg. 27 mg (1.4 mEq) Ca++/mL. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH (5.5 to 7.5). 2.04 mOsmol/mL (calc.). Medication and fluid path are sterile and non pyrogenic if pouch is undisturbed and package is intact. Contains not more than 1000 mcg/L of Aluminum.

Single-dose syringe. Discard unused portion. For intravenous use only. Administer only by slow injection (not to exceed 1 mL/minute). **Usual dosage:** See insert. Store at 20°C to 25°C (68°F to 77°F); excursion permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature.]

Medefil, Inc.
Glendale Heights, IL 60139

Instructions on back side

P3027 Rev. 004

1.8 mm VOID TYPE

## Use Aseptic Technique

1. Remove plastic wrapping by peeling apart.

2. Press the plunger rod forward to relieve any resistance that may be present.

3. Remove tip cap. Press the plunger rod forward until air is expelled from the syringe.

NDC 64253-**900**-91
Rx Only

# 10% Calcium Chloride Injection, USP
## 1000 mg/10mL (100 mg/mL)

**FOR INTRAVENOUS USE ONLY**

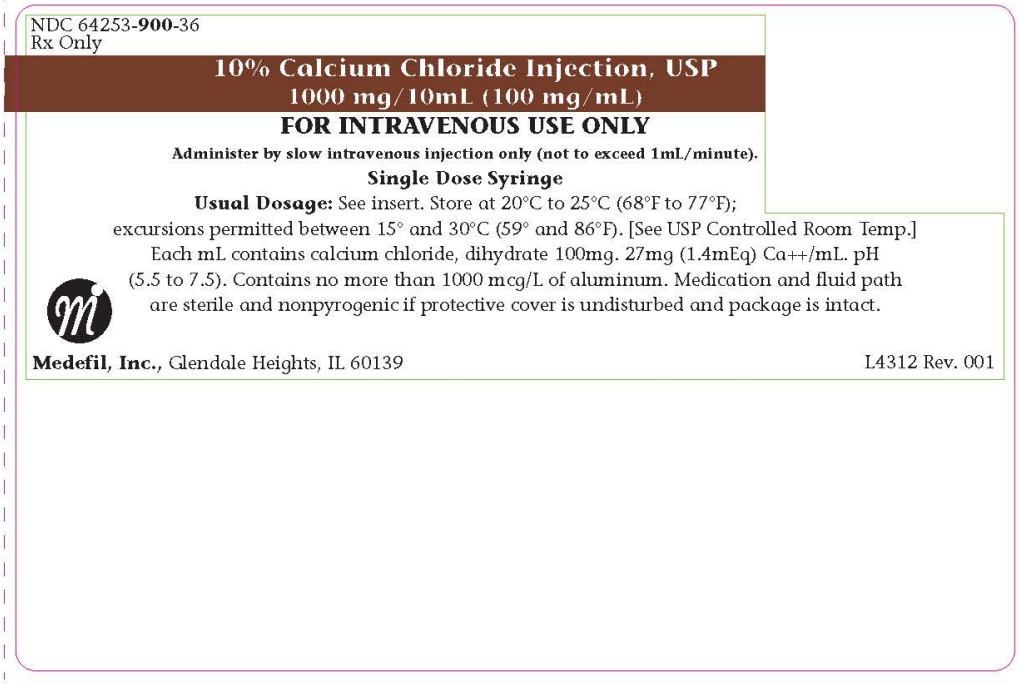
**Administer by slow intravenous injection only (not to exceed 1mL/minute).**

**Single Dose Syringe**

**Usual Dosage:** See insert. Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temp.]

Each mL contains calcium chloride, dihydrate 100mg. 27mg (1.4mEq) Ca++/mL. pH (5.5 to 7.5). Contains no more than 1000 mcg/L of aluminum. Medication and fluid path are sterile and nonpyrogenic if protective cover is undisturbed and package is intact.

**Medefil, Inc.,** Glendale Heights, IL 60139 L4345 Rev. 001




# CALCIUM CHLORIDE

calcium chloride injection injection, solution

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:64253-900 |
| **Route of Administration** | INTRAVENOUS | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **CALCIUM CHLORIDE** (UNII: M4I0D6VV5M) (CALCIUM CATION - UNII:2M83C4R6ZB, CHLORIDE ION - UNII:Q32ZN48698) | CALCIUM CHLORIDE | 100 mg in 1 mL |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:64253-900-36 | 60 in 1 BOX | 08/22/2019 | |
| **1** | NDC:64253-900-30 | 10 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | | |
| **2** | NDC:64253-900-91 | 10 in 1 BOX | 09/21/2020 | |
| **2** | | 10 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA211553 | 08/22/2019 | |

## Labeler - Medefil, Inc. (016448669)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Medefil, Inc. | | 016448669 | manufacture(64253-900) |

Revised: 6/2023 Medefil, Inc.