APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

CALCIUM GLUCONATE INJECTION FRESENIUS solution for injection

Calcium gluconate

Sugar free

Read all of this leaflet carefully before you receive CALCIUM GLUCONATE INJECTION FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What **CALCIUM GLUCONATE INJECTION FRESENIUS** is and what it is used for
2. What you need to know before you are given **CALCIUM GLUCONATE INJECTION FRESENIUS**
3. How to receive **CALCIUM GLUCONATE INJECTION FRESENIUS**
4. Possible side effects
5. How to store **CALCIUM GLUCONATE INJECTION FRESENIUS**
6. Contents of the pack and other information

1. What CALCIUM GLUCONATE INJECTION FRESENIUS is and what it is used for

CALCIUM GLUCONATE INJECTION FRESENIUS will be given to you when you have a deficiency of calcium in your blood (hypocalcaemia) either due to disease or other conditions.

2. What you need to know before you are given CALCIUM GLUCONATE INJECTION FRESENIUS

CALCIUM GLUCONATE INJECTION FRESENIUS should not be administered to you:

- if you are hypertensive (allergic) to calcium or any of the other ingredients of **CALCIUM GLUCONATE INJECTION FRESENIUS** (see section 6).
- if you have high calcium levels in your blood already (symptoms include increased thirst and urination, stomach pain, nausea (feeling sick), bone pain, muscle weakness, confusion and fatigue).
- if you have high levels of calcium in your urine (hypercalciuria) (symptoms in include blood in urine, pain with urination).
- if you have severe kidney disease and/or suffer from or have suffered from kidney stones in the past.
- if you have heart disease and/or being treated with digoxin or other digitalis type medicine (a kind of heart medicine).
- if also treated with the antibiotic ceftriaxone in premature and full-term new-borns (up to 28 days of age).
- if you have a child (less than 18 years of age) and require repeated or prolonged treatment.

Warnings and precautions

Special care should be taken with CALCIUM GLUCONATE INJECTION FRESENIUS:

Tell your doctor or health care provider before being given the injection:

- if you have kidney disease.
- if you have heart problems.
- if you have an electrolyte imbalance.
- if you have been diagnosed with cancer.

- if you suffer from deposition of calcium in the kidneys (nephrocalcinosis (symptoms include fever and chills, nausea (feeling sick) and vomiting (being sick), pain in the abdominal area, both sides of the back.
- if you have sarcoidosis (an inflammatory disease in which granulomas, or clumps of inflammatory cells, form in various organs of which symptoms include fatigue, weight loss, joint pain, dry mouth nosebleeds and abdominal swelling**.**
- if you are receiving adrenaline (epinephrine).
- if you are elderly.

Children and adolescents

Children and adolescents (under the age of 18) should not receive repeated or prolonged treatment with **CALCIUM GLUCONATE INJECTION FRESENIUS.**

Other medicines and CALCIUM GLUCONATE INJECTION FRESENIUS

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines and **CALCIUM GLUCONATE INJECTION FRESENIUS** may interfere with each other.

These include:

- digoxin – medicines used to treat heart problems
- medicines to treat high calcium levels
- water tablets (diuretics) – especially the thiazide type derivates, used to treat high blood pressure
- adrenaline (epinephrine) – medicine used to relieve severe allergic reactions
- magnesium – magnesium and calcium may reduce each other's effects
- calcium channel blockers – medicines used to treat high blood pressure
- ceftriaxone – a medicine to treat bacterial infections

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving **CALCIUM GLUCONATE INJECTION FRESENIUS**.

Driving and using machines

It is not always possible to predict to what extent **CALCIUM GLUCONATE INJECTION FRESENIUS** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **CALCIUM GLUCONATE INJECTION FRESENIUS** may affect you.

3. How to receive CALCIUM GLUCONATE INJECTION FRESENIUS

You will not be expected to give yourself **CALCIUM GLUCONATE INJECTION FRESENIUS**. It will be given to you by a person who is qualified to do so.

Dosage:

Your doctor will decide what the dose is and for how long you will receive **CALCIUM GLUCONATE INJECTION FRESENIUS**. This will vary from patient to patient. It will depend on your condition and other factors, such as your physical condition, weight, age as well as other medicines that you are taking at the time or after.

Method of administration:

CALCIUM GLUCONATE INJECTION FRESENIUS solution will be administered to you as an injection directly into the vein (intravenously).

If you have received more CALCIUM GLUCONATE INJECTION FRESENIUS than you should:

Since a healthcare professional will administer **CALCIUM GLUCONATE INJECTION FRESENIUS**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Missed CALCIUM GLUCONATE INJECTION FRESENIUS doses

Since a health care provider with administer **CALCIUM GLUCONATE INJECTION FRESENIUS**, it is unlikely that the dose will be missed.

4. Possible side effects

CALCIUM GLUCONATE INJECTION FRESENIUS can have side effects.

Not all side effects reported for **CALCIUM GLUCONATE INJECTION FRESENIUS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **CALCIUM GLUCONATE INJECTION FRESENIUS**, please consult your doctor, pharmacist, or other health care provider for advice.

If any of the following happens, stop receiving **CALCIUM GLUCONATE INJECTION FRESENIUS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **CALCIUM GLUCONATE INJECTION FRESENIUS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you

notice any of the following:

- A change in your heart rate – a slowing down or irregular heartbeat.
- Any kidney pain (symptoms include both sides of the back, or in the middle to upper back).
- Low blood pressure (symptoms include dizziness and light-headedness).
- Inability to stand without dizziness, cold clammy skin, looking pale

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice anything of the following:

Side effects with unknown frequency:

- Local reaction around the injection site such as redness, swelling, scarring and/or lump/abscess formation.
- A chalky taste in your mouth.
- Hot flushes.
- A warm burning sensation of the skin.
- Experience a loss of appetite.
- Feel listless.
- Have muscle and joint pains.
- Feel nauseous (feeling sick) or are vomiting (being sick).
- Are thirsty.
- Are producing large volumes of urine.
- Feel a change in your general wellbeing.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **CALCIUM GLUCONATE INJECTION FRESENIUS**.

Health care providers are asked to report any suspected adverse reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicines regulatory authority in the country where the product is marketed.

5. How CALCIUM GLUCONATE INJECTION FRESENIUS is stored

Store all medicines out of reach of children.

CALCIUM GLUCONATE INJECTION FRESENIUS will be stored in the pharmacy or in the hospital wards.

The injection is kept in a cool place at or below 30 °C.

6. Contents of the pack and other information

What CALCIUM GLUCONATE INJECTION FRESENIUS contains

The active substance is calcium gluconate.

Each 10 ml ampoule contains 902,5 mg calcium gluconate.

Other ingredients are calcium *d*-saccharate, water for injections.

What CALCIUM GLUCONATE INJECTION FRESENIUS looks like and contents of the pack

CALCIUM GLUCONATE INJECTION FRESENIUS contains a clear, colourless, semi-viscous solution.

CALCIUM GLUCONATE INJECTION FRESENIUS is presented in a 10 ml clear OPC glass ampoule (Type I).

Pack sizes: 10 ampoules in blister trays in a cardboard carton.

Holder of Certificate of Registration

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