Approved Patient Information Leaflet for CALCIUM CHLORIDE 10 % FRESENIUS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

CALCIUM CHLORIDE 10 % FRESENIUS solution for injection or infusion

Calcium chloride dihydrate

Sugar free

Read all of this leaflet carefully before you receive CALCIUM CHLORIDE 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 CHLORIDE FRESENIUS is and what it is used for
2. What you need to know before you receive CALCIUM CHLORIDE FRESENIUS
3. How to receive CALCIUM CHLORIDE FRESENIUS
4. Possible side effects
5. How to store CALCIUM CHLORIDE FRESENIUS

6. Contents of the pack and other information

1. What CALCIUM CHLORIDE FRESENIUS is and what it is used for

CALCIUM CHLORIDE FRESENIUS contains calcium chloride which is a mineral that occurs naturally in your body. Your heart and other muscles need calcium to work properly.

CALCIUM CHLORIDE FRESENIUS is used:

- To treat low levels of calcium in your body.
- In an emergency, during cardiac arrest, as calcium is essential for the heart muscles to maintain heart contractions.
- If there is too much potassium or magnesium in your blood.
- To relieve pain after lead poisoning.

2. What you need to know before you receive CALCIUM CHLORIDE FRESENIUS

CALCIUM CHLORIDE FRESENIUS should not be given to you if:

- You are hypersensitive (allergic) to calcium chloride or any of the other ingredients of CALCIUM CHLORIDE FRESENIUS (listed in section 6 of this leaflet).
- You suffer from ventricular fibrillation (where you heat has stopped beating effectively) or if you are taking medicines for heart problems (e.g. digoxin).
- Your blood has a tendency to clot easily.
- The calcium concentration in your blood or urine is too high.
- You have kidney failure or a weak kidney function, causing a low calcium concentration.
- You have osteoporosis (brittle bones due to loss of calcium), if due to lack of movement.
- You have certain bone cancers (ask your doctor).
- You have sarcoidosis (a rare, inflammatory disease that affects one or more organs but most commonly the lungs and lymph glands).

- You have taken high doses of vitamin D, or antacids.

Warnings and precautions:

Talk to your doctor before receiving CALCIUM CHLORIDE FRESENIUS if you:

- Have problems with your lungs or difficulty breathing.
- Have problems with your kidneys.
- Have, or have ever had, kidney stones.
- Have neoplastic disease (abnormal growth of cells, also known as a tumour) with an abnormally high concentration of parathyroid hormone in the blood.

Take special care with CALCIUM CHLORIDE FRESENIUS, if the injection is administered too rapidly. Signs or symptoms may include tingling sensations, a calcium taste (chalk-like taste) in the mouth, hot flushes, skin that may die and peel off, high blood pressure, fainting, low blood pressure, your heart beats more slowly, hardening of soft tissue. Speak to your doctor immediately if you experience any of these symptoms (also see section 4 below).

Your doctor may check the amount of electrolytes (e.g. calcium) in your blood at regular intervals.

Other medicines and CALCIUM CHLORIDE FRESENIUS:

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

Do not receive CALCIUM CHLORIDE FRESENIUS:

- If you are taking heart medicines such as digoxin (see section “CALCIUM CHLORIDE

FRESENIUS should not be given to you").

Tell your doctor if you are taking any of the following medicines:

- Vitamin D or bisphosphates (such as alendronate) used to treat osteoporosis (brittle bones).
- Diuretics (water tablets) used to treat high blood pressure, such as hydrochlorothiazide, indapamide.
- Antibiotics used to treat infections (such as ceftriaxone, oxytetracycline, tetracycline, cefalotin and clindamycin).
- Calcium channel blockers, used to treat heart problems or angina, such as verapamil, amlodipine, diltiazem.

CALCIUM CHLORIDE FRESENIUS with food and drink:

There are no known interactions between CALCIUM CHLORIDE FRESENIUS, food and drink.

Pregnancy and breastfeeding:

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 CHLORIDE FRESENIUS.

The safe use of CALCIUM CHLORIDE FRESENIUS during pregnancy and lactation has not been established.

Driving and using machines:

There is no known effect of CALCIUM CHLORIDE FRESENIUS on driving or using machines.

3. How to receive CALCIUM CHLORIDE FRESENIUS

Do not share any medicines prescribed for you with any other person.

You will not be expected to give yourself CALCIUM CHLORIDE FRESENIUS. It will be given to you by a doctor or a person who is qualified to do so.

Your doctor will administer CALCIUM CHLORIDE FRESENIUS very slowly through an injection or via an infusion into a vein (intravenously).

Your doctor will tell you how long your treatment with CALCIUM CHLORIDE FRESENIUS will last. If you have the impression that the effect of CALCIUM CHLORIDE FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more CALCIUM CHLORIDE FRESENIUS than you should:

Since a health care provider will administer CALCIUM CHLORIDE FRESENIUS, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdose.

The signs of an overdose may include reduced appetite, nausea, vomiting, constipation, muscle weakness, mental disturbances, feeling thirsty, urinate a lot, pain in your bones or kidney pain. In severe cases it could lead to your heart not beating properly and you could go into a coma. Please tell

your doctor as soon as possible as this may be a sign of overly high calcium blood levels (hypercalcaemia).

If you forget to receive CALCIUM CHLORIDE FRESENIUS:

Since a health care provider will administer CALCIUM CHLORIDE FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

CALCIUM CHLORIDE FRESENIUS can have side effects.

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

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

- Swelling of the 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 reaction to CALCIUM CHLORIDE FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Signs or symptoms of overdosage: reduced appetite, feeling sick, being sick, constipation, muscle weakness, mental disturbances, feeling thirsty, urinate a lot, pain in your bones or kidney pain. Also see section “If you receive more CALCIUM CHLORIDE FRESENIUS than you should” above.
- Signs or symptoms that you may experience if CALCIUM CHLORIDE FRESENIUS is injected too rapidly: tingling sensations, a calcium taste (chalk-like taste) in the mouth, hot flushes, skin that may die and peel off, high blood pressure, fainting, low blood pressure, your heart beats more slowly, hardening of soft tissue. Also see section “Warnings and precautions” above.

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

Tell your doctor if you notice any of the following:

Side effects occurring with unknown frequency:

- Nausea and vomiting.
- Tingling or burning sensation of the skin at the point of injection, hot flushes, sweating.
- A chalky taste in the mouth.

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

Reporting of side effects:

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

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA 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 CHLORIDE FRESENIUS.

5. How to store CALCIUM CHLORIDE FRESENIUS

- Store at or below 30 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the ampoule.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CALCIUM CHLORIDE FRESENIUS contains:

The active ingredient is calcium chloride dihydrate.

Each 10 ml ampoule contains 1 g calcium chloride dihydrate, equivalent to 6,803 millimoles or 13,606 milliequivalents of calcium.

The other ingredients are water for injection and hydrochloric acid (for pH-adjustment).

What CALCIUM CHLORIDE FRESENIUS looks like and contents of the pack:

A clear, colourless solution in 10 ml clear glass ampoules.

10 ml clear, Type 1 glass OPC ampoules, packed into a blister tray and outer carton.

Pack size: 10 ampoules per outer carton.

Holder of certificate of registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten

Port Elizabeth 6020

South Africa

Tel.: 041 403 1600

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