APPROVED PATIENT INFORMATION LEAFLET CLEAN COPY

SCHEDULING STATUS

S4

SUXAMETHONIUM CHLORIDE 100 mg /2 ml FRESENIUS

SOLUTION FOR INJECTION

Suxamethonium chloride

Sugar free

Read all of this leaflet carefully before you are given SUXAMETHONIUM CHLORIDE FRESENIUS injection

- 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 SUXAMETHONIUM CHLORIDE FRESENIUS is and what it is used for

SUXAMETHONIUM CHLORIDE FRESENIUS contains suxamethonium chloride which belongs to a group of medicines called peripherally-acting muscle relaxants. SUXAMETHONIUM CHLORIDE FRESENIUS is a short-term muscle relaxant used during anaesthesia.

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

SUXAMETHONIUM CHLORIDE FRESENIUS should not be administered to you:

- if there is a history of allergy to suxamethonium chloride, or to any of the ingredients of SUXAMETHONIUM CHLORIDE FRESENIUS;
- SUXAMETHONIUM CHLORIDE FRESENIUS has no effect on the level of consciousness and it should not be administered to you if you are not under full anaesthesia;
- if you suffered from burns and trauma within the last twelve months;
- if you have a condition where the muscles are affected;
- if there is a family history of very high body temperature;
- if you have a family history of heart disease or have abnormal heart rhythms, as the use of SUXAMETHONIUM CHLORIDE FRESENIUS may cause a heart attack;
- if you suffer from a muscle disorder called congenital myotonia which is a disorder that affects muscles used for movement (skeletal muscles). People with this condition experience bouts of sustained muscle tensing that prevent muscles from relaxing normally;
- if you suffer from muscle dystrophy, since administration may lead to heart attacks.

SUXAMETHONIUM CHLORIDE FRESENIUS should not be given through the same syringe or needle as other injectable medicine, as it may be incompatible with other medicines.

Warnings and precautions

Tell your doctor or health care provider before being given SUXAMETHONIUM CHLORIDE FRESENIUS if you have any of the following:

- Heart or lung disease, reduced plasma cholinesterase activity.
- Exposure to weedkillers, herbicides or insecticides in the home or agricultural environment.
- Asthma, because SUXAMETHONIUM CHLORIDE FRESENIUS can bring on an attack.
- Tetanus (muscle stiffness and pain, fever, sweating, muscle spasms).
- Liver or kidney problems.
- Tuberculosis (TB), a severe or chronic infection.
- Severe dehydration (increased thirst, dry mouth, swollen tongue, weakness, confusion).
- Any long-standing illness which has left you weak, cancer, anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration) or malnutrition.
- Any disease affecting your body's collagen or an underactive thyroid gland.
- Myasthenia gravis or Eaton-Lambert syndrome (autoimmune disease causing weakness of muscles).
- Glaucoma (increased pressure in the eye), eye wounds or recent eye surgery.
- Children may be at special risk from cardiac arrest associated with hyperkalaemia.
- The action of SUXAMETHONIUM CHLORIDE FRESENIUS on the heart may cause changes in cardiac rhythm including cardiac arrest.

Other medicines and SUXAMETHONIUM CHLORIDE FRESENIUS

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

- SUXAMETHONIUM CHLORIDE FRESENIUS may interact with certain antibiotics and various other medicines.
- Cyclophosphamide, mechlorethamine, triethylene-melamine and thiotepa (used to treat cancer).
- Anaesthetic medicines or other medicines used during surgery, such as painkillers.

- Medicines used to treat depression and/or anxiety, such as fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.
- Diphenhydramine or promethazine (used for allergic reactions, colds or sleeping).
- Oral contraceptives or medicines containing oestrogen.
- Cortisone-like medicines (used to treat inflamed areas of your body).
- Terbutaline or bambuterol (used to treat asthma and other breathing conditions).
- Metoclopramide (used to treat and prevent nausea (feeling sick) or vomiting (being sick)).
- Echothiophate eye drops (used to treat raised pressure in the eye (glaucoma)).
- Digoxin (used to treat disturbances in heartbeat rhythm).
- Lithium (used to treat some types of depression).
- Medicines containing magnesium.
- Azathioprine (used to stop your body rejecting a transplanted organ or for 'autoimmune' diseases, such as rheumatoid arthritis).
- Chloroquine or quinine (used to treat malaria).
- Antibiotics, such as gentamycin, clindamycin, lincomycin, amikacin, tobramycin, tetracyclines and polymyxins (used to treat infection).
- Quinidine, procainamide, verapamil, beta-blockers, lidocaine, procaine (used to control heart rhythm disorders, high blood pressure or chest pain).
- Inhalation anaesthetics.

SUXAMETHONIUM CHLORIDE FRESENIUS with food and drink

There are no known interactions between SUXAMETHONIUM 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 SUXAMETHONIUM CHLORIDE FRESENIUS.

Driving and using machines

SUXAMETHONIUM CHLORIDE FRESENIUS will always be used in combination with a general anaesthetic and therefore the usual precautions relating to performance of tasks following general anaesthesia apply.

3. How to receive SUXAMETHONIUM CHLORIDE FRESENIUS

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

Your doctor will decide what the dose is and for how long you will receive SUXAMETHONIUM CHLORIDE FRESENIUS.

Do not share medicine prescribed for you with others.

If you receive more SUXAMETHONIUM CHLORIDE FRESENIUS than you should

Since a healthcare provider will administer SUXAMETHONIUM CHLORIDE FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive SUXAMETHONIUM CHLORIDE FRESENIUS

Since a healthcare provider will administer SUXAMETHONIUM CHLORIDE FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

SUXAMETHONIUM CHLORIDE FRESENIUS can have side effects.

Not all side effects reported for SUXAMETHONIUM CHLORIDE FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SUXAMETHONIUM CHLORIDE FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving SUXAMETHONIUM 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.
- Severe rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SUXAMETHONIUM 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:

- interruption or stop of function of the heart;
- fatal heart complications;
- slowed heart rate or irregular heartbeat;
- blood disorders;
- breathing distress caused by narrowing of the airway;
- increased body temperature with or without high muscular tension.

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

Tell your doctor if you notice any of the following:

Side effects reported frequently:

- rise in intraocular pressure;
- skin flushing
- rise in intra-gastric pressure may occur;
- increase in bowel movements and in gastric and salivary secretions;
- salivary gland enlargement;
- muscle damage and muscular pain after operation;
- loss of muscle function or feeling after childbirth;
- fever.

Side effects reported less frequently:

- prolonged neuromuscular blockade;
- breathing interruptions during sleep;
- increased potassium levels;
- high or low blood pressure;
- increased bronchial secretions;
- spasm of the jaw muscles;
- increased blood acidity.

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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)

found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SUXAMETHONIUM CHLORIDE FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or 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.

5. How to store SUXAMETHONIUM CHLORIDE FRESENIUS

- Store in a refrigerator (2 – 8 °C). Protect from light.
- STORE ALL MEDICINE OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- 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 SUXAMETHONIUM CHLORIDE FRESENIUS contains

- The active ingredient is suxamethonium chloride.
- The other ingredients are sodium hydroxide (for pH-adjustment) and water for injection.

What SUXAMETHONIUM CHLORIDE FRESENIUS looks like and contents of the pack

Clear, colourless solution in amber glass ampoules.

10 x 2 ml amber glass ampoules packed in a cardboard carton.

The ampoules are packed into PVC blister trays and the trays are packed into cardboard cartons.

Pack size: Packs of ten per carton.

Holder of certificate of registration and manufacturer

Fresenius Kabi Manufacturing SA (Pty) Ltd

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This leaflet was last revised on

13 May 2025

REGISTRATION NUMBER

M/17.1/270

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.