

Package leaflet: Information for the patient

Suxamethonium Chloride 50mg/ml Solution for Injection

suxamethonium chloride

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Suxamethonium Chloride 50mg/ml Solution for Injection. It will be referred to as Suxamethonium Chloride for ease hereafter.

What is in this leaflet:

1. What Suxamethonium Chloride is and what it is used for
2. What you need to know before you are given Suxamethonium Chloride
3. How Suxamethonium Chloride will be given to you
4. Possible side effects
5. How to store Suxamethonium Chloride
6. Contents of the pack and other information

1. What Suxamethonium Chloride is and what it is used for

Suxamethonium Chloride belongs to a group of medicines called muscle relaxants. Their effect is to block the connection between the nerves and certain muscles, which relaxes these muscles by temporarily paralysing them. This effect helps surgeons when performing operations.

This medicine can also be used when a patient is put on a ventilator to control breathing. During this procedure, it is necessary for the muscles used for breathing to be paralysed. Suxamethonium Chloride can also reduce the intensity of muscle contractions associated with drug-induced convulsions or with electroconvulsive therapy (ECT).

2. What you need to know before you are given Suxamethonium Chloride

You should not be given Suxamethonium Chloride

- if you are allergic to Suxamethonium Chloride, any other muscle relaxants or any of the other ingredients of this medicine (listed in section 6)
- if you or your family have reacted badly to an anaesthetic before such as a very high body temperature (malignant hyperthermia)
- if you have severe liver or kidney problems
- if you have a deficiency of an enzyme, pseudocholinesterase which breaks down suxamethonium in the body
- if you have had a major accident, operation or severe burns within the last three months
- if you have not been able to move for a long time such as to allow a broken bone to mend or a long period of bed rest
- if you have high levels of potassium in your blood (hyperkalaemia)
- if you have recently had an eye injury
- if you suffer from a problem caused by too much pressure in your eye called 'glaucoma'
- if you or any of your family have a disease of the muscles or nerves, such as a muscle wasting disease, paralysis, motor neurone disease, muscular dystrophy or cerebral palsy.

If any of the above apply to you or if you are not sure, talk to your doctor, nurse or member of the operating theatre staff before you are given Suxamethonium Chloride.

Warnings and precautions

Suxamethonium Chloride should only be given to you by a person who is qualified to do so. It will not be used on its own to put you asleep before an operation. It will be used in combination with other medicines.

Suxamethonium Chloride rapidly decomposes in the body and this can lead to rapid recovery of muscle function.

Talk to your doctor, nurse or member of the operating theatre staff before you are given Suxamethonium Chloride:

- if you are pregnant or have given birth in the last six weeks
- if you have tetanus, an infection which occurs through wound contamination
- if you have tuberculosis or other severe or long standing infection
- if you have had any long standing illness which has left you weak
- if you suffer from cancer
- if you have decreased number of red blood cells or hemoglobin concentration, a condition known as anaemia
- if you are undernourished
- if you have liver or kidney problems
- if you have auto-immune diseases, for example, multiple sclerosis
- if you have an underactive thyroid gland, a condition known as myxoedema
- if you have muscle disease, for example, myasthenia gravis
- if you have recently had a blood transfusion or a heart-lung by pass
- if you have been in contact with insecticides
- if you have ever had an allergic reaction to any muscle relaxant which was given as part of an operation.
- if you are suffering from an imbalance in your body's blood chemistry
- if you have a bone injury or muscle tightness in the area of the injury
- if you recently received radiation therapy
- if you suffer from severe burns

If you are elderly (over 65 years) check with your doctor, nurse or pharmacist before having this medicine as it may be linked to a temporary problem with the rate or rhythm of the heartbeat, especially if you are also taking medicines similar to digitalis

Suxamethonium Chloride should only be used when absolutely essential in vulnerable patients

Make sure your doctor is aware of these situations before you are given this injection.

Children

Care should be taken before administering Suxamethonium Chloride to children.

Other medicines and Suxamethonium Chloride

Tell your doctor, nurse if you are taking, have recently taken or might take any other medicines. This includes any herbal products or medicines bought without a prescription. This is because these medicines can affect how well Suxamethonium Chloride works or can cause side effects.

In particular tell your doctor, nurse or member of the operating theatre staff if you are taking any of the following:

- anaesthetics such as propofol, ketamine, propanidid, lignocaine and procaine or other medicines used during surgery such as pain killers (morphine, pethidine and pancuronium) or drugs to reverse their effects (called morphine antagonists)
- medicines used to treat Alzheimer's disease, such as donepezil, galantamine and tetrahydroaminoacridine (Tacrine hydrochloride)
- medicines for raised pressure in the eye (glaucoma) such as ecothiophate eye drops
- medicines for coughs, cold, sleeping or tablets for allergies
- medicines used to treat malaria, containing chloroquine or quinine. Quinine is sometimes used for night cramps.

- oral contraceptives
- medicines for treating asthma and other breathing conditions e.g. terbutaline, Bambuterol.
- medicines containing metoclopramide (used to treat and prevent feeling or being sick)
- medicines for treating cancer (cytotoxic drugs) such as cyclophosphamide, triethylene-melanine, chlorethamine, tretamine and thiotepa
- medicines for mental problems including phenelzine, lithium, chlorpromazine or promazine
- medicines containing magnesium (such as some laxatives or antacids)
- medicines containing oestrogens
- medicines containing steroids (used for inflammatory conditions e.g. rheumatism etc),
- oxytocin (to contract the womb),
- some non-penicillin antibiotics (for infection) e.g. clindamycin, polymyxins, and aminoglycosides, vancomycin, piperacillin,
- medicines used to treat disturbances in heartbeat rhythm (antiarrhythmic drugs), angina or high blood pressure such as beta-blockers, verapamil, digoxin, procainamide or quinidine
- aprotinin (to reduce bleeding)
- medicines used to treat myasthenia gravis such as neostigmine, pyridostigmine, physostigmine and edrophonium (known as acetylcholinesterase inhibitors)
- medicines used to control your blood pressure during surgery such as trimetaphan
- medicines that can affect the way your body fights disease (immunosuppressants) such as azathioprine. These can be used to stop your body rejecting a transplanted organ or for 'auto-immune' diseases such as rheumatoid arthritis
- medicines used to treat depression and/or anxiety SSRIs (selective serotonin reuptake inhibitors) including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Suxamethonium Chloride should only be used during pregnancy when your doctor decides the benefits to you are greater than any possible risk to the unborn baby.

Breast-feeding

There is insufficient information to say whether this medicine passes in to breast milk. It is recommended not to breast feed for at least 24 hours following administration of Suxamethonium Chloride.

Ask your doctor for advice before taking any medicine.

Driving and using machines:

It can be dangerous to drive or operate machinery too soon after having had an operation. Your doctor will tell you how long to wait before you can drive or use machinery.

Information on sodium content

Suxamethonium Chloride contains less than 1mmol sodium (23mg) per dose, i.e. essentially "sodium free".

3. How Suxamethonium Chloride will be given to you

You will never be expected to give yourself this medicine. It will always be given to you by a person who is qualified to do so.

Suxamethonium Chloride can be given:

- as a single injection into your vein (intravenous bolus injection)
- as a continuous infusion into your vein. This is where the drug is slowly given to you over a long period of time.

Your doctor will decide the way you are given the drug and the dose you will receive. It will depend on:

- your age
- your body weight
- the amount of muscle relaxation you require
- your expected response to the medicine.

It may be administered as an injection. The anaesthetist will make sure that you are asleep before this muscle relaxant is administered.

If you take more Suxamethonium Chloride than you should

As the injection will be administered by an anaesthetist, it is unlikely that you will be given more than is necessary. In case of an overdose, the muscle will stay relaxed for longer than required.

If you have any further questions on the use of this product ask your doctor or nurse.

4. Possible Side Effects

Like all medicines this medicine can cause side-effects although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are very rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Inform your doctor or nurse immediately if you experience:

- heart problems including changes in the way in which your heart beats or your heart stops beating
- difficulty in breathing or temporary loss of breath

The following side effects have also been reported:

Very common (may affect more than 1 in 10 people)

- abdominal cramps or pain and a feeling of nausea or “fullness”
- visible twitching of muscle under the skin
- excessive production of saliva
- muscle pain after the operation - your doctor will monitor you for this.

Common (may affect up to 1 in 10 people)

- raised pressure of fluid in the eye which may cause headache or blurred vision
 - speeding up or slowing down of your heart rate
 - skin flushing
 - skin rash
 - laboratory tests revealing high level of potassium in your blood
 - high/low blood pressure
 - laboratory tests revealing protein in the blood or urine due to muscle damage
 - muscle damage which may make your muscles ache or feel tender, stiff and weak.
- Your urine may also look dark or be red or cola coloured.

Rare (may affect up to 1 in 1,000 people)

- abnormal heart rhythm
- difficulty in opening your mouth.

Very rare (may affect less than 1 in 10,000 people)

- high body temperature.

When you wake up after the anaesthetic, if you notice any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SUXAMETHONIUM CHLORIDE

Keep this medicine out of the sight and reach of children.

Your doctor or nurse will know how to store this medicine properly.

Keep the container in the outer carton in order to protect from light.

The ampoules containing the injection solution are stored in their original packaging at a temperature between 2 and 8°C. Do not freeze. The expiry date (EXP) is printed on the label and the carton. The first 2 digits indicate the month and the remaining digits indicate the year of expiry. Do not use this medicine after the expiry date which is stated on the ampoule. Once opened, any unused liquid should be discarded.

Do not use if the ampoule is damaged or if the contents are discoloured or deteriorated.

The solution should not be mixed with any other drugs.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. Contents of the pack and other information

What Suxamethonium Chloride contains

- The active substance is Suxamethonium Chloride. There is 100mg of Suxamethonium Chloride in 2ml of the injection.
- Other ingredients of the solution are Sodium acetate and water for injections.

What Suxamethonium Chloride looks like and contents of pack

Suxamethonium Chloride is a clear, colourless sterile solution. Each glass ampoule (small bottle) contains 2ml with 100mg respectively of the active ingredient, Suxamethonium Chloride. These ampoules are then packed in to cardboard boxes. Each box contains 10 ampoules.

Marketing authorisation holder

Mercury Pharmaceuticals (Ireland) Ltd,
4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

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