Suxamethonium Chloride 50mg/ml Solution for Injection

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

Key points
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you have 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 in this leaflet.

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 to use Suxamethonium Chloride
4. Possible side effects
5. How to store Suxamethonium Chloride
6. Contents of the pack and other information

Suxamethonium Chloride is a muscle relaxant. It blocks the effect of acetylcholine on the muscles of the body so that they stop working. As a result, the patient becomes unconscious and is not aware of the operation. The anaesthetist can control the amount of muscle relaxation by giving larger or smaller doses of Suxamethonium Chloride.

Suxamethonium Chloride can be given:
- as an injection
- by inhalation
- for short periods as a muscle relaxant during a general anaesthetic
- to reverse the effects of curare-like drugs
- to reverse the effects of other similar drugs (called "morpine antagonists")
- 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 had a previous adverse reaction to this medicine
- 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 allergy 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 any further questions, ask your doctor or nurse.

Suxamethonium Chloride rapidly decomposes in the body and this can lead to rapid recovery of muscle function. The anaesthetist will monitor your vital signs so that they can detect and treat any changes that may occur.

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

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 releases 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 had a previous adverse reaction to this medicine
- 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 are suffering from an imbalance in your body’s blood chemistry
- if you have any further questions, ask your doctor or nurse.

Suxamethonium Chloride can be given:
- if you are suffering from an imbalance in your body’s blood chemistry
- if you have been in contact with insecticides
- if you have recently had a blood transfusion or a heart-lung bypass
- if you have muscle disease, for example, myasthenia gravis
- if you have liver or kidney problems
- if you have anaemia
- if you are pregnant or have given birth in the last six weeks
- 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.

If you get any side effects, talk to your doctor or pharmacist, this includes any possible side effects not listed in this leaflet. See section 4.

Patients
- Suxamethonium Chloride rapidly decomposes in the body and this can lead to rapid recovery of muscle function. The anaesthetist will monitor your vital signs so that they can detect and treat any changes that may occur.
- 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 or if you are taking, have recently taken or might take any other medicines. This includes any medicines that you take for colds or other minor illnesses.

Ask your doctor for advice before taking any medicine.

If you take more Suxamethonium Chloride than you should

Effects not listed in this leaflet. See section 4.

If you have any further questions on the use of this product ask your doctor or nurse.
• medicines that can affect the way your body fights disease (immunosuppressants) such as azathioprine.
• 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 no sufficient information to say whether this medicine passes into 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.

Suxamethonium Chloride contains less than 1 millimol (1 mmol) 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:
• 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 responses 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

Ask 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 weakness, 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.

The following side effects have also been reported:
• abnormality in the way in which your heart beats or your heart stops beating (malignant hyperthermia)
• difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body)
• 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
• eye irritation
• raised pressure of fluid in the ear which may cause headache or blurred vision
• visible twitching of muscle under the skin
• muscle pain after the operation - your doctor will monitor you for this.

Rare (may affect up to 1 in 1,000 people)
• abnormal heart rhythm
• 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
• difficulty in opening your mouth

Very rare (may affect less than 1 in 10,000 people)
• high body temperature.

If 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 pharmacist, this includes any possible side effects not listed in this leaflet. You can also report side effects directly. [See details below]

United Kingdom: Yellow Card Scheme at www.mhra.gov.uk/yellercard

Ireland: HPAA Pharmacovigilance

Eastwall Terrace

IFL, Dublin 2
Tel: +353 1 6764671
Fax: +353 1 6764517
Website: www.hpaa.ie

E-mail: medsafe@hpaa.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. THE STORAGE OF SUXAMETHONIUM CHLORIDE

• Keep this medicine out of the sight and reach of children.
• Do not store above 30°C.
• Your doctor or nurse will know how to store this medicine properly.
• Keep the container out of the sunlight in order to protect from light.

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 injection.

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 into cardboard boxes. Each box contains 10 ampoules.

Marketing authorisation holder

United Kingdom: Mercury Pharma International Ltd, 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

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

Manufacturer

B. Braun Melagup, Molelweg 2, 12937 Berlin, Germany.

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