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 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).

Do not take Suxamethonium Chloride

- if you are allergic to Suxamethonium Chloride, any other muscle relaxants or any of the other ingredients of Suxamethonium Chloride (listed in section 6)
- 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 an underactive thyroid gland, a condition known as myxoedema
- if you have auto-immune diseases, for example, multiple sclerosis
- if you have liver or kidney problems
- if you are undernourished
- if you have anaemia
- 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 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, peripheral motor neuron disease, muscular dystrophy or cerebral palsy
- 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, peripheral motor neuron disease, muscular dystrophy or cerebral palsy
- 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 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

Talk to your doctor, nurse or member of the operating theatre staff before taking Suxamethonium Chloride:
- if you are pregnant or have given birth in the last six weeks
- if you have a disease of the muscles or nerves, such as a muscle wasting disease, peripheral motor neuron disease, muscular dystrophy or cerebral palsy.
- if you have a disease of the muscles or nerves, such as a muscle wasting disease, peripheral motor neuron disease, muscular dystrophy or cerebral palsy.
- 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, peripheral motor neuron disease, muscular dystrophy or cerebral palsy
- 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.

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 other relevant hospital staff member 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:

- medicines used to treat Alzheimer’s disease, such as donepezil, galantamine and tacrine
- aprotinin (to reduce bleeding)
- 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)
itching (especially affecting your whole body) should be reported to a doctor immediately. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or
All medicines can cause allergic reactions although serious allergic reactions are very rare.

How to take Suxamethonium Chloride

To use all medicines Suxamethonium Chloride 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. The following side effects have also been reported:

Very common (affects more than 1 in 10 people)
- abdominal cramps or pain and a feeling of nausea or "fullness"
- vomiting
- feeling faint
- excessive sweating
- muscle pain after the operation - your doctor will monitor you for this.

Common (affects less than 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 (affects less than 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 (affects less than 1 in 10,000 people)
- high body temperature
- balancing difficulties

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

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 1mmol sodium (23mg) per dose, i.e. essentially "sodium free".

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.

Merkur Pharma International Ltd.,
4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

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4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufactured
Blaen Miskunen A/O, Mistelweg 2ff, Berlin 47, D12357 Germany.

This leaflet was last revised in: March 2015.

• medicines used to control your blood pressure during surgery such as trileptan
• 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

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.

5. HOW TO STORE SUXAMETHONIUM CHLORIDE

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

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.

• medicines used to control your blood pressure during surgery such as trileptan
• 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

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE SUXAMETHONIUM CHLORIDE

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 into cardboard boxes. Each box contains 10 ampoules.

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