PACKAGE LEAFLET: INFORMATION FOR THE USER

Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion

suxamethonium chloride dihydrtate

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, nurse or member of the operating theatre staff.
- If you get any side effects, talk to your doctor, nurse, or member of the operating theatre staff. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion is and what it is used for

Suxamethonium Chloride Injection / Infusion contains a medicine called suxamethonium chloride. This belongs to a group of medicines called muscle relaxants.

Suxamethonium Chloride is used:
- to relax muscles during operations on adults and children

Ask your doctor if you would like more explanation about this medicine.

2. What you need to know before you are given Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion

You should not be given Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion if:
- you are allergic to suxamethonium chloride, or any of the other ingredients of this medicine (listed in section 6)
- your doctor has told you that you suffer from abnormal cholinesterase activity (cholinesterase is an enzyme that breaks down acetylcholine)
- you or any of your family have a history of abnormally high body temperature (hyperthermia)
- you have abnormally high levels of potassium in your blood (hyperkalaemia)
- you or any of your family have a disease causing weakness of the muscles (myotonia congenita or dystrophia myotonica)
- you have muscle weakness and wasting of muscle tissue (Duchenne muscular dystrophy)

Warnings and precautions

This medicine will be given to you by a qualified anaesthetist, along with other medicines to help you sleep. Ventilation equipment will be used to help you breathe.

Talk to your doctor, nurse or member of the operating theatre staff before having this medicine if you:
- are suffering from an infection that causes muscle stiffness (tetanus)
- are suffering from tuberculosis
- feel unwell
- have a fever
- have cancer
- suffer from a blood disease known as anaemia
- suffer from a lack of proper nutrition or an inability to absorb nutrients from food (malnutrition)
- have serious liver or kidney problems
- suffer from a disease caused by the body attacking itself (autoimmune disease) such as a disease of the thyroid gland (myxoedema)
- suffer from diseases that cause problems with the joints (collagen disease)
- suffer from heart problems (including heart attacks, heart disease or an irregular heart beat)
- are having or have had in the past treatment to your blood known as plasmapheresis therapy
- have had any head injuries
- are recovering from major trauma or severe burns
- have suffered a spinal cord injury, nerve injury or sudden muscle wasting
- have a muscle disease, for example, myasthenia gravis
- recently had an eye injury
- have glaucoma
- ever had an allergic reaction to any muscle relaxant which was given as part of an operation
- have not been able to walk for a long period of time
- have severe blood poisoning (sepsis)

Children

Extra care or monitoring must be carried out on infants and children given suxamethonium. If any of the above apply to you or your child, please consult your doctor.

Other medicines and Suxamethonium Chloride Injection/Infusion

Tell your doctor, nurse or other relevant hospital staff member if you are taking or have recently taken any other medicines
- anti-arrhythmics (drugs used to alter the rhythm of the heart) e.g. lidocaine, procaine and cocaine.
- antibacterials (drugs able to kill bacteria) e.g. neomycin, vancomycin and polymyxin B
- anticholinesterases (drugs used to treat muscle problems) such as neostigmine
- ecothiopate, a medicine used to treat raised pressure in the eye (glaucoma)
- metoclopramide, a medicine used to stop you feeling or being sick
- phenelzine, a medicine used to treat depression (monoamine oxidase inhibitor)
- promazine, a medicine used to treat restlessness and agitation
- medicines used to treat malaria such as quinine and chloroquine
- tacrine, a medicine used to treat Alzheimers disease
- ACE inhibitors
- antiepileptics (drugs used to stop fits) e.g. carbamazepine and phenytoin
- antineoplastics (drugs used to treat cancer) e.g. cyclophosphamide and tretamine
- benzodiazepines (drugs which help you to relax) e.g. diazepam and midazolam
- calcium-channel blockers (drugs which reduce the strength of the heart) e.g. nifedipine, verapamil or dantrolene.
- cardiac glycosides (drugs which increase heart muscle contraction) e.g. digoxin
- cytotoxics (a type of medicine used to treat cancer) e.g. cyclophosphamide and thiotepa
- general anaesthetics (drugs used to put you to sleep for surgery) e.g. propofol, fentanyl citrate-droperidol (Innovar) and ether
- magnesium salts (a dietary supplement)
- medicines that affect the nervous system (parasympathomimetics and sympathomimetics) e.g. demecarium, neostigmine, donepezil, bambuterol.

Tell your doctor if you have recently been exposed to pesticides e.g. sheep dip.

Tell your doctor if you have recently had a blood transfusion

If you have any doubts about whether this medicine should be administered to you, consult your doctor or nurse.

Pregnancy & breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant ask your doctor for advice before this medicine is given to you.

Driving and using machines

Do not drive or operate machinery immediately after having been operated on because it can be dangerous. Your doctor will tell you how long you should wait before you can drive and use machinery.

3. How Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion is given

Suxamethonium Chloride Injection/Infusion will be given to you as an injection into your vein (intravenously).

Your doctor will decide the dose and duration of treatment appropriate to your intervention. It will depend on:
- your body weight
- the amount of muscle relaxation you require
- your expected response to the medicine.

Suxamethonium Chloride will always be given under carefully controlled conditions. If you have any further questions on the use of this medicine, ask your doctor.

Adults, the elderly and adolescents over 12 years

By intravenous injection:
1mg per kilogram of bodyweight
Supplementary doses of around 50% to 100% of the initial dose given at 5 to 10 minute intervals will maintain muscle relaxation.
By intravenous infusion (drip):
0.1-0.2% solution, 2.5 to 4mg per minute

The maximum total dose is 500 mg.

Children 1 to 12 years
By intravenous injection:
1-2mg per kilogram of bodyweight.

Infants (under 1 year): 2mg per kilogram.

If you are given too much Suxamethonium Chloride 50 mg/ml Solution for Injection / infusion

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too little or too much, however, tell your doctor or nurse if you have any concerns.

Continued Overleaf

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4. Possible Side Effects

Like all medicines, Suxamethonium Chloride Injection / Infusion can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor, nurse or other relevant hospital staff member. This includes any possible side effects not listed in this leaflet.

Very rarely, a sudden and severe allergic reaction to suxamethonium chloride can occur. If you get any of the following symptoms tell your doctor or nurse immediately:

- shortness of breath, wheezing or trouble breathing
- swelling of your eyelids, face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- a collapse.

There are other serious side effects that you and your doctor must look out for.

You must tell your doctor or nurse straight away if you have any of the following:

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
- 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
- skin flushing
- skin rash
- high level of potassium in your blood
- speeding up or slowing down of your heart rate
- 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
- heart problems including changes in the way in which your heart beats or your heart stopping beating
- difficulty in breathing or temporary loss of breath
- difficulty in opening your mouth.

Very rare (may affect up to 1 in 10,000 people)

- high body temperature.

Other side effects include:

Not known: frequency cannot be estimated from the available data

- excessive production of saliva
- high/low blood pressure

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion

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

You should not be given Suxamethonium Chloride Injection / Infusion after the expiry date which is printed on the carton and ampoule label after 'EXP'. The doctor or nurse will check that the expiry date on the label has not been passed before administering the injection to you. The expiry date refers to the last day of that month.

Store in a refrigerator, between 2 and 8°C. Do not freeze.

Store in the original package to protect from light.

This product should be used immediately after opening.

Do not use this medicine if you notice any discoloration or there are particles in it.

Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will throw away any medicine that is no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion contains

The active substance is suxamethonium chloride dihydrate 50 mg/ml.

The other ingredients are hydrochloric acid (for pH adjustment), water for injections.

What Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion looks like and contents of the pack

Suxamethonium Chloride injection / infusion is a clear, colourless solution supplied in a clear glass 2ml ampoule. Each 2 ml ampoule contains 100 mg of suxamethonium chloride dihydrate (equivalent to 73.1 mg of Suxamethonium). 10 ampoules are packed in one carton.

Marketing Authorisation Holder:
Martindale Pharmaceuticals Limited
Bampton Road, Harold Hill,
Romford, Essex RM3 8UG

Manufacturer:
Macarthys Laboratories Limited t/a Martindale Pharma
Bampton Road, Harold Hill,
Romford, Essex RM3 8UG

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at the above address.

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MARTINDALE PHARMA
Bampton Road, Harold Hill, Romford, RM3 8UG, UK

The following information is intended for medical or healthcare professionals only

Suxamethonium Chloride 50 mg/ml Solution for Injection / Infusion Used for muscle relaxation during general anaesthesia

Posology and method of administration

Use by intravenous injection

Adults and Children over 12 years

The dose is dependent on body weight, the degree of muscular relaxation required, the route of administration, and the response of individual patients.

To achieve endotracheal intubation Suxamethonium Chloride is usually administered intravenously in a dose of 1mg/kg. This dose will usually produce muscular relaxation in about 30 to 60 seconds and has a duration of action of about 2 to 6 minutes. Larger doses will produce more prolonged muscular relaxation but doubling the dose does not necessarily double the duration of relaxation. Supplementary doses of Suxamethonium Chloride of 50% to 100% of the initial dose administered at 5 to 10 minute intervals will maintain muscle relaxation during short surgical procedures performed under general anaesthesia.

The total dose of Suxamethonium Chloride should not exceed 500mg.

Children, Infants and young children are more resistant to Suxamethonium Chloride compared with adults.

Children 1 to 12 years

1-2mg/kg by intravenous injection.

Infants, under 1 year

2mg/kg by intravenous injection.

Use by intravenous infusion

Suxamethonium Chloride may be given by intravenous infusion as a 0.1% to 0.2% solution, diluted in 5% glucose solution or sterile isotonic saline solution, at a rate of 2.5 to 4mg per minute. The infusion rate should be adjusted according to the response of individual patients.

Elderly

As for adults.

The elderly may be more susceptible to cardiac arrhythmias, especially if digitalis-like drugs are also being taken.

Method of administration:

By bolus injection or infusion.

Overdose

Profound, prolonged muscle paralysis with respiratory depression are manifestations of a suxamethonium overdose. Ventilatory support is required.

The use of neostigmine and other cholinesterase inhibitors should be avoided, as these prolong the depolarising effect of suxamethonium chloride.

The decision to use neostigmine to reverse a Phase II suxamethonium-induced block depends on the judgement of the clinician in the individual case. Valuable information in regard to this decision will be gained by monitoring neuromuscular function. If neostigmine is used, its administration should be accompanied by appropriate doses of an anticholinergic agent such as atropine.

Incompatibilities

Suxamethonium Chloride must not be mixed with other medicinal products except those mentioned under special precautions for disposal and handling.

Suxamethonium Chloride is acidic and should not be mixed with highly alkaline solutions, e.g. barbiturates.

Special precautions for disposal and other handling

Use once and discard any remaining solution.

Suxamethonium Chloride may be given by intravenous infusion as a 0.1% to 0.2% solution, diluted in 5% glucose solution or sterile isotonic saline solution, at a rate of 2.5 to 4mg per minute. The infusion rate should be adjusted according to the response of individual patients.

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100mm Measurement Verification Bar

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MARTINDALE PHARMA

DEVELOPMENT ARTWORK

Component Code: D05018

Prod: Suxamethonium chloride 50mg/ml PIL

Paper Size: 340 x 260mm

Version Control	Date	By
Version A :	23/01/18	NF
Version B:	25/01/19	SS
Version C:	02/04/19	NF
Version D:	10/01/20	NF
Version E:		
Version F:		
Version G:		
Version H:		
Version I:		
Version J:		
Version K:		
Version L:		
Version M:		
Version N:		
Version O:		

me&you
1 Blighs Road, Sevenoaks, Kent, TN13 1DA, UK
t: +44 (0) 1732 749 748
e: nick@meandyou.co.uk
e: sarah@meandyou.co.uk
www.meandyou.co.uk