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

**1. WHAT IS SUXAMETHONIUM CHLORIDE AND WHAT IS IT 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**

- **Problems to watch for before taking Suxamethonium Chloride**
  - Muscle relaxant effects may last for some time after the operation.
  - You may still feel tired and sore when you go home.
  - You may have difficulty in opening your mouth.
  - You may have difficulty in breathing or temporary loss of breath.
  - You may have heart problems including changes in the way in which your heart beats or your heart stops beating.
  - You may have high/low blood pressure.
  - You may have a skin rash.
  - You may have speeding up or slowing down of your heart rate.

**3. HOW SUXAMETHONIUM CHLORIDE WILL BE GIVEN TO YOU**

- Suxamethonium Chloride should only be given to you by a person who is qualified to do so. It will not be used to help you 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.

- Your doctor, nurse or member of the operating theatre staff will be given Suxamethonium Chloride.

**4. POSSIBLE SIDE EFFECTS**

**Common (may affect up to 1 in 10 people)**

- Muscle pain after the operation - your doctor will monitor you for this.
- Visible twitching of muscle under the skin.
- Abdominal cramps or pain and a feeling of nausea or "fullness".
- High blood pressure.
- Skin rash.
- Difficulty in opening your mouth.
- Difficulty in breathing or temporary loss of breath.
- Heart problems including changes in the way in which your heart beats or your heart stops beating.
- Skin rash.
- Speeding up or slowing down of your heart rate.

**Uncommon (may affect up to 1 in 100 people)**

- Muscle cramps.
- High blood pressure.
- Difficulty in breathing or temporary loss of breath.
- Heart problems including changes in the way in which your heart beats or your heart stops beating.
- Skin rash.
- Speeding up or slowing down of your heart rate.

**Rare (may affect up to 1 in 10,000 people)**

- High blood pressure.
- Difficulty in breathing or temporary loss of breath.
- Heart problems including changes in the way in which your heart beats or your heart stops beating.
- Skin rash.
- Speeding up or slowing down of your heart rate.

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

- High blood pressure.
- Difficulty in breathing or temporary loss of breath.
- Heart problems including changes in the way in which your heart beats or your heart stops beating.
- Skin rash.
- Speeding up or slowing down of your heart rate.

**5. POSSIBLE INTERACTIONS WITH OTHER MEDICINES**

Suxamethonium Chloride is a paralyzing agent. It works by blocking the transmission of nerve impulses to the muscles. This effect may be enhanced by other medicines (e.g. digitalis plants such as foxglove) which may also block the transmission of nerve impulses to the muscles. This effect can be partially reversed by giving a medicine called a morphine antagonist (e.g. naloxone). This effect may also be enhanced by medicines that are used to treat disturbances of heartbeat rhythm (antiarrhythmic drugs), angina or high blood pressure such as beta-blockers, verapamil, digoxin, propranolol or quinidine.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

- **Leaves 1 and 2:** Suxamethonium Chloride 50mg/ml Solution for Injection.
- **Leaves 3-6:** Information on the use of this medicine.
- **Leaves 7-8:** How to store Suxamethonium Chloride.
- **Leaves 9-10:** List of ingredients.
- **Leaves 11-12:** Advice on the environment.
- **Leaves 13-14:** How to return any unused medicine.
- **Leaves 15-16:** How to use this leaflet.

**PACKAGING AND STORAGE**

- **Packaging:** Ampoules containing 2ml with 100mg respectively of the active ingredient, Suxamethonium Chloride. These ampoules are then placed in a carton for transport.
- **Storage:** Store 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.

**RECORDING YOUR MEDICATIONS**

- When taking any medicine, it is important to keep a record of the name, dose and time of administration of your medicines. This will help you to avoid taking medicines that may interact with each other.
- It is advisable to keep a complete list of all medicines you are taking or have been prescribed in the past.
- It is important to inform your doctor, nurse or pharmacist before taking any medicine.

**RECOGNITION OF MEDICATIONS**

- **Ampoules:** Suxamethonium Chloride 50mg/ml Solution for Injection is a clear, colourless solution for injection.
- **Pack:** Black carton and colourless glass ampoules.

**RECOGNITION OF PATIENT INFORMATION**

- **Patient Information Leaflet:** Suxamethonium Chloride 50mg/ml Solution for Injection.
- **Packaging:** Black carton and colourless glass ampoules.

**PACKAGING:**

- **Packaging:** Ampoules containing 2ml with 100mg respectively of the active ingredient, Suxamethonium Chloride. These ampoules are then placed in a carton for transport.
- **Storage:** Store 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.
• 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, eszopiclone.

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 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 is 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 1mg/ml 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 before 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 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.

The following side effects have also been reported:

• abdominal pain or cramps
• abdominal cramps or pain and a feeling of nausea or "fullness"
• inability to move legs
• skin rash
• itching
• abdominal cramps or pain and a feeling of nausea or "fullness"
• abdominal pain or cramps
• skin rash
• itching
• abdominal cramps or pain and a feeling of nausea or "fullness"

Rare (may affect up to 1 in 1,000 people)
• abdominal pain or cramps
• 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 blood pressure
• abdominal pain or cramps
• skin rash

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, tell your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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

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 (EDP) is printed on the label and the carton. The 2 is indicative of 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 store above 25°C.

• 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 (EDP) is printed on the label and the carton. The 2 is indicative of 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 store above 25°C.

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.

One pack contains 10 ampoules of 2ml with 100mg respectively of the active substance, Suxamethonium Chloride.

One pack contains 10 ampoules.

Marketing authorisation holder
Merck Sharp & Dohme Limited Ltd.
204, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer
B. Braun Melsungen AG, Melsungen 2, 35509, Germany.

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