

[Aspen]

Package Leaflet: Information for the patient

Anectine 50 mg / ml 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, 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 Anectine is and what it is used for
2. What you need to know before you are given Anectine
3. How Anectine is given
4. Possible side effects
5. How to store Anectine
6. Contents of the pack and other information

1. What Anectine is and what it is used for

Anectine contains a medicine called suxamethonium chloride. This belongs to a group of medicines called muscle relaxants.

Anectine is used:

- to relax muscles during operations on adults and children
- to help insert a tube into the windpipe (endotracheal intubation), if a person needs help to breathe
- to reduce how strongly your muscles contract

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

2. What you need to know before you are given Anectine

You should not be given Anectine if:

- you are allergic to suxamethonium chloride, any other muscle relaxants or any of the other ingredients of Anectine Injection (listed in section 6)
- you or your family have reacted badly to an anaesthetic before such as a very high body temperature (malignant hyperthermia)
- you have an inherited enzyme abnormality, pseudocholinesterase which breaks down suxamethonium in the body
- you have had a major accident, operation or severe burns within the last three months
- 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
- you have high levels of potassium in your blood (hyperkalaemia)
- you have recently had an eye injury
- you suffer from a problem caused by too much pressure in your eye called 'glaucoma'
- 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 Anectine.

Warnings and precautions

Talk to your doctor, nurse or member of the operating theatre staff before having this medicine if you have:

- tetanus, an infection which occurs through wound contamination
- tuberculosis or other severe or long-standing infection
- had any long-standing illness which has left you weak
- cancer
- anaemia
- malnutrition
- liver or kidney problems
- auto-immune diseases, for example, multiple sclerosis
- an underactive thyroid gland, a condition known as myxoedema
- muscle disease, for example, myasthenia gravis
- recently had a blood transfusion or a heart-lung bypass
- been in contact with insecticides
- ever had an allergic reaction to any muscle relaxant which was given as part of an operation.

Other medicines and Anectine

Tell your doctor, nurse or other relevant hospital staff member if you are taking or have recently taken any other medicines. This includes any herbal products or medicines bought without a prescription. This is because these medicines can affect how well Anectine 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, or other medicines used during surgery such as painkillers
- 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
- oral contraceptives
- medicines for treating asthma and other breathing conditions
- medicines containing metoclopramide, used to treat and prevent feeling or being sick
- medicines for treating cancer (cytotoxic drugs)
- medicines for mental problems
- medicines containing magnesium
- medicines containing oestrogens
- medicines containing steroids
- antibiotics
- medicines used to treat disturbances in heartbeat rhythm (antiarrhythmic drugs)
- medicines used to treat myasthenia gravis
- medicines used to control your heart
- medicines used to control your blood pressure during surgery
- 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, are planning to have a baby or have given birth in the last six weeks, ask your doctor for advice before taking this 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 and use machinery.

3. How Anectine is given

How your injection is given

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.

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

If you receive more Anectine than you should

Anectine will always be given under carefully controlled conditions. However, if you think that you have been given more than you should tell your doctor or nurse immediately.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine 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 Anectine 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:**

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
- 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.

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

- high body temperature.

Other side effects include:

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)

- skin flushing
- skin rash
- high level of potassium in your blood
- high/low blood pressure

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

- difficulty in opening your mouth.

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 at: www.mhra.gov.uk/yellowcard.

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

5. How to store Anectine

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date which is stated on the pack after “EXP”. 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
- 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. This will help protect the environment.

6. Contents of the pack and other information

What Anectine contains

- The active substance is 50 mg / ml suxamethonium chloride
- The other ingredient is water for injection.

What Anectine looks like and contents of the pack

Anectine Injection is supplied as a clear, colourless solution in a neutral glass, 2 ml ampoule.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Aspen Pharma Trading Limited, 3016 Lake Drive, City West Business Campus, Dublin 24, Ireland
Service-Tel: 0800 008 7392 (+ 44 1748 828 391)

Manufacturer: GlaxoSmithKline Manufacturing S.p.A., Strada Provinciale Asolana 90, 43056 San Polo di Torrile, Parma, Italy

or

Aspen Pharma Ireland Limited, One George’s Quay Plaza, Dublin 2, Ireland

or

Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name: **Anectine 50 mg / ml Injection**
Reference number: PL 39699/0098

This is a service provided by the Royal National Institute of Blind People.

The Information provided applies only to Anectine 50 mg / ml Injection.

This leaflet was last revised in May 2020.

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[Aspen]

The following information is intended for medical or healthcare professionals only

Anectine 50 mg / ml Injection
suxamethonium chloride

Product Summary

1. NAME OF THE MEDICINAL PRODUCT

Anectine 50 mg/ml Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Suxamethonium chloride Injection BP 100 mg in 2 ml.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Used in anaesthesia as a muscle relaxant to facilitate endotracheal intubation, mechanical ventilation and a wide range of surgical and obstetric procedures.

It is also used to reduce the intensity of muscular contractions associated with pharmacologically or electrically-induced convulsions.

4.2 Posology and method of administration

Usually by bolus intravenous injection.

Adults: 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 Anectine is usually administered intravenously in a dose of 1 mg/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 Anectine 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.

For prolonged surgical procedures Anectine 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 4 mg per minute. The infusion rate should be adjusted according to the response of individual patients.

The total dose of Anectine given by repeated intravenous injection or continuous infusion should not exceed 500 mg per hour.

Children: Infants and young children are more resistant to Anectine compared with adults.

The recommended intravenous dose of Anectine for neonates and infants is 2 mg/kg. A dose of 1 mg/kg in older children is recommended.

When Anectine is given as intravenous infusion in children, the dosage is as for adults with a proportionately lower initial infusion rate based on body weight.

Anectine may be given intramuscularly to infants at doses up to 4 to 5 mg/kg and in older children up to 4 mg/kg. These doses produce muscular relaxation within about 3 minutes. A total dose of 150 mg should not be exceeded.

Use in the elderly: Dosage requirements of Anectine in the elderly are comparable to those for younger adults.

The elderly may be more susceptible to cardiac arrhythmias, especially if digitalis-like drugs are also being taken. (see section 4.4).

Use in renal impairment: A normal single dose of suxamethonium injection may be administered to patients with renal insufficiency in the absence of hyperkalaemia. Multiples or larger doses may cause clinically significant rises in serum potassium and should not be used (see section 4.3 and 4.4).

Use in hepatic impairment: Termination of the action of suxamethonium is dependent on plasma cholinesterase, which is synthesised in the liver. Although plasma cholinesterase levels often fall in patients with liver disease, with the exception of severe hepatic failure, levels are seldom low enough to significantly prolong suxamethonium-induced apnoea (see section 4.4).

Use in patients with reduced plasma cholinesterase: Patients with reduced plasma cholinesterase activity may experience prolonged and intensified neuromuscular blockade following administration of suxamethonium. In these patients it may be advisable to administer reduced doses of suxamethonium injection (see section 4.3, 4.4 and 4.5).

Monitoring advice: Monitoring of neuromuscular function is recommended during infusion of suxamethonium injection or if suxamethonium injection is to be administered in relatively large cumulative doses over a relatively short period of time in order to individualise dosage requirements (see section 4.4).

Instructions to open the ampoule: See section 6.6 Special precautions for disposal and other handling for further information.

4.3 Contraindications

Anectine has no effect on the level of consciousness and should not be administered to a patient who is not fully anaesthetised.

Hypersensitivity to suxamethonium may exist in rare instances, and Anectine should not be administered to patients known to be hypersensitive to the drug.

As suxamethonium can act as a trigger of sustained myofibrillar contraction in susceptible individuals, Anectine is contraindicated in patients with a personal or family history of malignant hyperthermia. If this condition occurs unexpectedly, all anaesthetic agents known to be associated with its development (including Anectine) must be immediately discontinued, and full supportive measures must be immediately instituted. Intravenous dantrolene sodium is the primary specific therapeutic drug and is recommended as soon as possible after the diagnosis is made.

Anectine is contraindicated in patients known to have an inherited atypical plasma cholinesterase activity.

An acute transient rise in serum potassium often occurs following the administration of Anectine in normal individuals; the magnitude of this rise is of the order of 0.5 mmol/litre. In certain pathological states or conditions this increase in serum potassium following Anectine administration may be excessive and cause serious cardiac arrhythmias and cardiac arrest. For this reason the use of Anectine is contraindicated in:

- patients recovering from major trauma or severe burns; the period of greatest risk of hyperkalaemia is from about 5 to 70 days after the injury and may be further prolonged if there is delayed healing due to persistent infection.

- patients with neurological deficits involving acute major muscle wasting (upper and/or lower motor neurone lesions); the potential for potassium release occurs within the first 6 months after the acute onset of the neurological deficit and correlates with the degree and extent of muscle paralysis. Patients who have been immobilised for prolonged periods of time may be at similar risk.
- patients with pre-existing hyperkalaemia. In the absence of hyperkalaemia and neuropathy, renal failure is not a contra-indication to the administration of a normal single dose of Anectine Injection, but multiple or large doses may cause clinically significant rises in serum potassium and should not be used.

Suxamethonium causes a significant transient rise in intra-ocular pressure, and should therefore not be used in the presence of open eye injuries or where an increase in intra-ocular pressure is undesirable unless the potential benefit of its use outweighs the potential risk to the eye.

Anectine should be avoided in patients with a personal or family history of congenital myotonic diseases such as myotonia congenita and dystrophia myotonica since its administration may on occasion be associated with severe myotonic spasms and rigidity.

Anectine should not be used in patients with skeletal muscle myopathies e.g. Duchenne muscular dystrophy since its administration may be associated with malignant hyperthermia, ventricular dysrhythmias and cardiac arrest secondary to acute rhabdomyolysis with hyperkalaemia.

4.4 Special warnings and precautions for use

Anectine paralyses the respiratory muscles as well as other skeletal muscles but has no effect on consciousness.

Anectine should be administered only by or under close supervision of an anaesthetist familiar with its action, characteristics and hazards, who is skilled in the management of artificial respiration and only where there are adequate facilities for immediate endotracheal intubation with administration of oxygen by intermittent positive pressure ventilation.

High rates of cross-sensitivity (greater than 50%) between neuromuscular blocking agents have been reported. Therefore, where possible, before administering suxamethonium, hypersensitivity to other neuromuscular blocking agents should be excluded. Suxamethonium, should only be used when absolutely essential in susceptible patients. Patients who experience a hypersensitivity reaction under general anaesthesia should be tested subsequently for hypersensitivity to other neuromuscular blockers.

Suxamethonium injection should not be mixed with any other drug prior to its administration.

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

During prolonged administration of Anectine, it is recommended that the patient is fully monitored with a peripheral nerve stimulator in order to avoid overdosage.

Anectine is rapidly hydrolysed by plasma cholinesterase which thereby limits the intensity and duration of the neuromuscular blockade.

Individuals with decreased plasma cholinesterase activity exhibit a prolonged response to suxamethonium. Approximately 0.05% of the population has an inherited cause of reduced cholinesterase activity.

Prolonged and intensified neuromuscular blockade following Anectine Injection may occur secondary to reduced plasma cholinesterase activity in the following states or pathological conditions:

- physiological variation as in pregnancy and the puerperium (see section 4.6)
- genetically determined abnormal plasma cholinesterase (see section 4.3)
- severe generalised tetanus, tuberculosis, other severe or chronic infections

- following severe burns (see section 4.3)
- chronic debilitating disease, malignancy, chronic anaemia and malnutrition
- end-stage hepatic failure, acute or chronic renal failure (see section 4.2)
- auto-immune diseases: myxoedema, collagen diseases
- iatrogenic: following plasma exchange, plasmapheresis, cardiopulmonary bypass, and as a result of concomitant drug therapy (see section 4.5).

If Anectine is given over a prolonged period, the characteristic depolarising neuromuscular (or Phase I) block may change to one with characteristics of a non-depolarising (or Phase II) block. Although the characteristics of a developing Phase II block resemble those of a true non-depolarising block, the former cannot always be fully or permanently reversed by anticholinesterase agents. When a Phase II block is fully established, its effects will then usually be fully reversible with standard doses of neostigmine accompanied by an anticholinergic agent.

Tachyphylaxis occurs after repeated administration of Anectine.

Muscle pains are frequently experienced after administration of suxamethonium and most commonly occur in ambulatory patients undergoing short surgical procedures under general anaesthesia. There appears to be no direct connection between the degree of visible muscle fasciculation after Anectine administration and the incidence or severity of pain. The use of small doses of non-depolarising muscle relaxants given minutes before suxamethonium administration has been advocated for the reduction of incidence and severity of suxamethonium-associated muscle pains. This technique may require the use of doses of suxamethonium in excess of 1 mg/kg to achieve satisfactory conditions for endotracheal intubation.

Caution should be exercised when using suxamethonium in children, since paediatric patients are more likely to have an undiagnosed myopathy or an unknown predisposition to malignant hyperthermia and rhabdomyolysis, which places them at increased risk of serious adverse events following suxamethonium (see section 4.3 and section 4.8).

In patients with severe sepsis, the potential for hyperkalaemia seems to be related to the severity and duration of infection.

It is inadvisable to administer Anectine to patients with advanced myasthenia gravis. Although these patients are resistant to suxamethonium they develop a state of Phase II block which can result in delayed recovery. Patients with myasthenic Eaton-Lambert syndrome are more sensitive than normal to Anectine, necessitating dosage reduction.

In healthy adults, Anectine occasionally causes a mild transient slowing of the heart rate on initial administration. Bradycardias are more commonly observed in children and on repeated administration of suxamethonium in both children and adults. Pre-treatment with intravenous atropine or glycopyrrolate significantly reduces the incidence and severity of suxamethonium-related bradycardia.

In the absence of pre-existing or evoked hyperkalaemia, ventricular arrhythmias are rarely seen following suxamethonium administration. Patients taking digitalis-like drugs are however more susceptible to such arrhythmias. The action of suxamethonium on the heart may cause changes in cardiac rhythm including cardiac arrest.

4.5 Interactions with other medicinal products and other forms of interaction

Certain drugs or chemicals are known to reduce normal plasma cholinesterase activity and may therefore prolong the neuromuscular blocking effects of Anectine. These include:

- organophosphorous insecticides and metrifonate
- ecothiopate eye drops
- trimetaphan
- specific anticholinesterase agents: neostigmine, pyridostigmine, physostigmine, edrophonium; tacrine hydrochloride
- cytotoxic compounds: cyclophosphamide, mechlorethamine, triethylene-melamine, and thiotepa

- psychiatric drugs: phenelzine, promazine and chlorpromazine
- anaesthetic agents and drugs: ketamine, morphine and morphine antagonists, pethidine, pancuronium, propanidid
- selective serotonin reuptake inhibitors (SSRI).

Other drugs with potentially deleterious effects on plasma cholinesterase activity include aprotinin, diphenhydramine, promethazine, oestrogens, oxytocin, high-dose steroids, and oral contraceptives, terbutaline and metoclopramide.

Certain drugs or substances may enhance or prolong the neuromuscular effects of Anectine by mechanisms unrelated to plasma cholinesterase activity. These include:

- magnesium salts
- lithium carbonate
- azathioprine
- quinine and chloroquine
- antibiotics such as the aminoglycosides, clindamycin and polymyxins
- antiarrhythmic drugs: quinidine, procainamide, verapamil, beta-blockers, lidocaine and procaine
- volatile inhalational anaesthetic agents: halothane, enflurane, desflurane, isoflurane, diethylether and methoxyflurane have little effect on the Phase I block of Anectine Injection but will accelerate the onset and enhance the intensity of a Phase II suxamethonium-induced block.

Patients receiving digitalis-like drugs are more susceptible to the effects of suxamethonium-exacerbated hyperkalaemia.

4.6 Fertility, pregnancy and lactation

No studies of the effect of suxamethonium on female fertility or pregnancy have been performed.

Suxamethonium has no direct action on the uterus or other smooth muscle structures. In normal therapeutic doses it does not cross the placental barrier in sufficient amounts to affect the respiration of the infant.

The benefits of the use of suxamethonium as part of a rapid sequence induction for general anaesthesia normally outweigh the possible risk to the foetus.

Plasma cholinesterase levels fall during the first trimester of pregnancy to about 70 to 80% of their pre-pregnancy values; a further fall to about 60 to 70% of the pre-pregnancy levels occurs within 2 to 4 days after delivery. Plasma cholinesterase levels then increase to reach normal over the next 6 weeks. Consequently, a high proportion of pregnant and puerperal patients may exhibit mildly prolonged neuromuscular blockade following Anectine Injection.

It is not known whether suxamethonium or its metabolites are excreted in human milk.

4.7 Effects on ability to drive and use machines

This precaution is not relevant to the use of suxamethonium injection. Suxamethonium will always be used in combination with a general anaesthetic and therefore the usual precautions relating to performance of tasks following general anaesthesia apply.

4.8 Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Estimated frequencies were determined from published data. Frequencies are defined as follows: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$).

Immune system disorders

Very rare Anaphylactic reactions.

Eye disorders

Common Increased intraocular pressure.

Cardiac disorders

Common Bradycardia, tachycardia.
Rare Arrhythmias (including ventricular arrhythmias), cardiac arrest.

There are case reports of hyperkalaemia-related cardiac arrests following the administration of suxamethonium to patients with congenital cerebral palsy, tetanus, Duchenne muscular dystrophy, and closed head injury. Such events have also been reported rarely in children with hitherto undiagnosed muscular disorders.

Vascular disorders

Common Skin flushing.

Hypertension and hypotension have also been reported.

Respiratory, thoracic and mediastinal disorders

Rare Bronchospasm, prolonged respiratory depression†, apnoea†.

† Individuals with decreased plasma cholinesterase activity exhibit a prolonged response to suxamethonium. Approximately 0.05% of the population has an inherited cause of reduced cholinesterase activity (please refer to section 4.4).

Gastrointestinal disorders

Very common Increased intragastric pressure.

Excessive salivation has also been reported

Skin and subcutaneous tissue disorders

Common Rash.

Musculoskeletal and connective tissue disorders

Very common Muscle fasciculation, post-operative muscle pains (please refer to section 4.4).
Common Myoglobinaemia#, myoglobinuria#.
Rare Trismus

Rhabdomyolysis has also been reported (see section 4.3 and section 4.4).

General disorders and administration site conditions

Very rare Malignant hyperthermia (please refer to section 4.4).

Investigations

Common Transient blood potassium increase.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Apnoea and prolonged muscle paralysis are the main serious effects of overdosage. It is essential, therefore, to maintain the airway and adequate ventilation until spontaneous respiration occurs.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Peripherally acting muscle relaxants, choline derivatives, ATC code: M03AB01.

Short-acting depolarising neuromuscular blocking agent.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

Genotoxicity:-

No bacterial mutation assays have been conducted.

There are some data to suggest a weak clastogenic effect in mice, but not in patients who had received suxamethonium chloride.

Carcinogenicity:-

Carcinogenicity studies have not been performed.

Embryo-foetal Development:-

Animal reproduction studies have not been conducted with suxamethonium. It is also not known whether suxamethonium can affect reproductive capacity or cause foetal harm when administered to a pregnant woman.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections EP.

6.2 Incompatibilities

None known.

Suxamethonium injection should not be mixed with any other drug prior to its administration.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store between 2 and 8 °C. Do not freeze. Keep in the outer carton to protect from light.

6.5 Nature and contents of container

Neutral glass. 2ml ampoules.

6.6 Special precautions for disposal and other handling

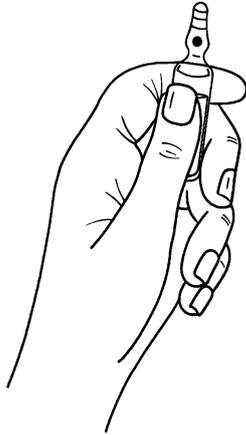
For intravenous injection under medical direction.

Instructions to open the ampoule

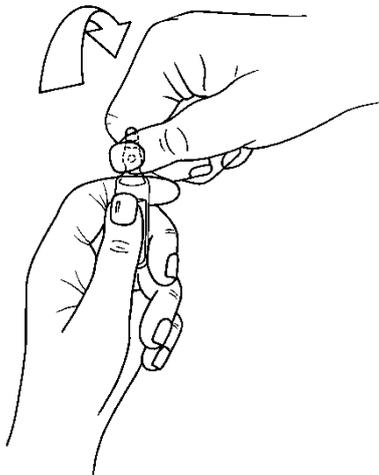
Ampoules are equipped with the OPC (One Point Cut) opening system and must be opened using the following instructions:

- hold with the hand the bottom part of the ampoule as indicated in picture 1
- put the other hand on the top of the ampoule positioning the thumb above the coloured point and press as indicated in picture 2

Picture 1



Picture 2



7. MARKETING AUTHORISATION HOLDER

Aspen Pharma Trading Limited, 3016 Lake Drive, City West Business Campus, Dublin 24, Ireland
Service-Tel: 0800 008 7392 (+ 44 1748 828 391)

8. MARKETING AUTHORISATION NUMBER

PL 39699/0098

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 August 1985/16 May 2008

This leaflet was last revised in May 2020.