Patient Information Leaflet: Information for the user

Anectine 50 mg/ml Solution for Injection or Infusion
(suxamethonium chloride)

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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 have Anectine

Do not use Anectine if:
- you are allergic to suxamethonium chloride or any of the other ingredients of Anectine injection (listed in section 6).
- you or a family member have reacted badly to an anaesthetic before, such as a very high body temperature (malignant hyperthermia) or a long pause in breathing (prolonged apnoea).
- you have severe liver or kidney problems.
- 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 a family member have an inherited condition which effects the muscles such as myotonia congenita or dystrophia myotonica.
- you have a disease of the muscles or nerves, such as a muscle wasting disease, paralysis, motor neurone disease, muscular dystrophy or cerebral palsy.
- you have a genetic defect in an enzyme found in the liquid part of your blood (plasma cholinesterase).

Anectine should not be given to you unless you are fully anaesthetised.

Do not use Anectine if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before you have Anectine.

Warnings and precautions
Anectine should only be given to you by a person who is qualified to do so. It **will not** be used on its own to put you asleep before an operation. It **will** be used in combination with other medicines.

Anectine rapidly decomposes in the body and this can lead to rapid recovery of muscle function.

Talk to your doctor, nurse or pharmacist before having Anectine if you have:
- blood poisoning
- an allergy to any other muscle relaxants
- tetanus, an infection which occurs through wound contamination.
- tuberculosis or other severe or long standing infection
- severe burns
- had any long standing illness which has left you weak
- you are suffering from cancer
- you are suffering from anaemia
- you suffer from malnutrition
- liver or kidney problems
- auto-immune diseases, for example, multiple sclerosis
- an underactive thyroid gland, a condition known as myxoedema
- collagen diseases such as systemic lupus erythematosus, rheumatoid arthritis, rheumatic fever, polymyositis, and dermatomyositis
- muscle disease, for example, myasthenia gravis
- recently had a blood transfusion or a heart-lung by pass
- been in contact with insecticides
- recently received radiation therapy
- unexplained loss of weight
- an imbalance in your body's blood chemistry
- a bone injury or muscle tightness in the area of the injury
- given birth in the last six weeks

If you are elderly (over 65 years) check with your doctor, nurse or pharmacist before having this medicine as it may be linked to a temporary problem with the rate or rhythm of the heartbeat, especially if you are also taking medicines similar to digitalis.

Children
Care should be taken when using Anectine in newborn babies and children.

Other medicines and Anectine
Please tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because these medicines can affect how well Anectine works or can cause side effects.

In particular tell your doctor, nurse or pharmacist if you are taking any of the following:

- anaesthetics, or other medicines used during surgery such as ketamine, pethidine, pancuronium, morphine and morphine antagonists, halothane, enflurane, desflurane, isoflurane, diethylether and methoxyflurane
- medicines for raised pressure in the eye (glaucoma) such as ecothiophate eye drops
- medicines for allergies such as diphenhydramine or promethazine
- medicines for treating asthma and other breathing conditions such as terbutaline
- medicines containing metoclopramide, used to treat and prevent feeling or being sick

- medicines for treating cancer (cytotoxic drugs) such as cyclophosphamide, mechlorethamine, triethylenemelamine and thio-tepa
- medicines for treating mental illnesses, such as phenelzine, promazine, chloropromazine, lithium carbonate or selective serotonin reuptake inhibitors
- medicines containing magnesium such as indigestion medicines
- medicines containing oestrogen such as oral contraceptive pills
- medicines containing steroids
- antibiotics such as aminoglycosides, clindamycin and polymyxins
- medicines used to treat disturbances in heartbeat rhythm such as quinidine, procainamide, verapamil, lidocaine, procaine and beta blockers (anti-arrhythmic drugs)
- medicines used to treat myasthenia gravis such as neostigmine, pyridostigmine, edrophonium, and tacrine hydrochloride
- medicines used to treat Alzeimher's disease such as physostigmine,
- medicines used to control your heart such as digitalis
- medicines used during surgery to control your blood pressure, such as trimetaphan, or to reduce bleeding, such as aprotinin
- 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

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 or pharmacist for advice before taking this medicine.

Driving and using machines
Do not drive or operate machinery after having this medicine. Your doctor will tell you when it is safe to do so again. It is recommended that you arrange for someone to accompany you home from the hospital.

3. How to have Anectine

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.

In children, Anectine can also be given as a single injection into a muscle (intramuscular bolus injection).

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 immediatley.

4. Possible side effects

Like all medicines, Anectine can cause side effects, although not everybody gets them.
The following side effects may happen with this medicine:

Allergic reactions are very rare (they affect less than 1 in 10,000 people).
If you have an allergic reaction, tell your doctor or nurse straight away. The signs may include:
- sudden wheeziness, chest pain or chest tightness
- swelling of your eyelids, face, lips, mouth or tongue
- a lumpy skin rash or 'hives' anywhere on your body
- a collapse

Very common (affects 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 (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
- high level of potassium in your blood
- high/low blood pressure
- protein in the blood or urine due to muscle damage

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 stopping 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

Frequency not known
- excessive production of saliva
- breakdown of muscle fibres (rhabdomyolysis) which may make your muscles ache or feel tender, stiff and weak. Your urine may also look dark or be red or cola coloured

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:medsafety@hpra.ie.

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Anectine

- Keep out of the sight and reach of children.
- Do not use Anectine after the expiry date which is stated on the pack. The expiry date refers to the last day of the month.
- Anectine is supplied as a clear, colourless solution. Do not use if it looks different to normal.
- Store in a refrigerator, between 2 and 8°C. Do not freeze.
- Store in the original package to protect from light.

6. Contents of the pack and other information

What Anectine contains
- The active substance is suxamethonium chloride.
- The other ingredient is water for injections.

What Anectine looks like and contents of the pack
Anectine 50 mg/ml Solution for Injection or Infusion is supplied as a clear, colourless solution in a neutral glass, 2 ml ampoule. Each 2 ml ampoule contains 100 mg Suxamethonium Chloride. Each pack contains 5 ampoules.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland
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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY
(Please refer to the Summary of Product Characteristics for further information)

Anectine 50 mg/ml Solution for Injection or Infusion (suxamethonium chloride)

Pharmaceutical form

Anectine 50 mg/ml Solution for Injection or Infusion

Posology and method of administration

Instructions for use

The dose of Anectine Injection is dependent on age, body weight, the degree of muscle relaxation required and the route of administration.

The usual method of Anectine Injection administration is by bolus intravenous injection.

Use by intravenous bolus injection
Dosage in adults: A single intravenous dose of suxamethonium chloride dihydrate of approximately 1mg/kg bodyweight will usually provide profound neuromuscular blockade and good conditions for tracheal intubation within 30-60 seconds of its administration. The duration of clinically useful neuromuscular relaxation produced by this dose is on average 2-6 minutes, although wide inter-patient variability exists.

Larger single doses of Anectine Injection may slightly accelerate the speed at which neuromuscular paralysis develops, and will produce longer durations of clinically useful muscle relaxation but not in a direct dose-dependent manner; doubling the dose of Anectine Injection does not necessarily double the duration of relaxation.

Supplementary intravenous doses of Anectine Injection of 50-100% of the initial dose may be administered for the maintenance of muscle relaxation during short surgical or other procedures performed under general anaesthesia, at intervals of 5-10 minutes as required. During administration of Anectine Injection by repeated intravenous bolus injection, the total dose should not exceed 500mg per hour.

Dosage in children: Compared with adults, infants and young children are more resistant to the neuromuscular blocking effects of suxamethonium on a mg per kg bodyweight basis.

In neonates and infants, the recommended intravenous bolus dose of Anectine Injection is 2mg/kg bodyweight. A dose of 1mg/kg bodyweight in an older child is recommended.

Dosage in the elderly: Dosage requirements of Anectine Injection in the elderly are comparable to those of younger adults (see Dosage in adults).

Administration of Anectine Injection may be associated with transient cardiac arrhythmias; the elderly may be more susceptible to such arrhythmias especially if digitalis-like drugs are also being taken.

Use by intramuscular bolus dosing
Dosage in children: Anectine Injection may be administered intramuscularly at doses up to 4-5mg/kg bodyweight in infants and up to 4mg/kg bodyweight in older children. The onset of clinically useful neuromuscular relaxation following intramuscular administration of Anectine Injection is apparent within about 3 minutes.

Not more than 150mg total dose should be given.

Use by intravenous infusion
Dosage in adults and children: For prolonged surgical procedures in adults and older children, Anectine Injection may be administered by intravenous infusion as a 0.1% (1mg/ml) or 0.2% (2mg/ml) solution of suxamethonium chloride dihydrate in sterile 5% glucose solution or sterile 0.9% w/v saline solution.

In adults, the initial rate of infusion of Anectine Injection should be 36 micrograms/kg/min to 57 micrograms/kg/min (2.15mg/kg/hr to 3.42mg/kg/hr). A proportionately lower initial infusion rate based on bodyweight should be used in children. The infusion rate should thereafter be adjusted in accordance with the response of each individual patient.

Dosage requirements of Anectine Injection may increase with time during intravenous infusion.

During administration of Anectine Injection by intravenous infusion, the total dose should not exceed 500mg per hour.

Dosage in the elderly: In the absence of specific dosage studies for the elderly, refer to Dosage in adults and children and Section 4.4 of the Summary of Product Characteristics.

Dosage in renal impairment: A normal single dose of Anectine 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.

Dosage 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, levels are seldom low enough to significantly prolong suxamethonium-induced apnoea.

Dosage in patient 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 dosages of Anectine Injection.

Monitoring advice: Monitoring of neuromuscular function is recommended during infusion of Anectine Injection or if Anectine Injection is to be administered in relatively large cumulative doses over a relatively short period of time in order to individualise dosage requirements.

Overdose

Symptoms and signs:
Apnoea and prolonged muscle paralysis are the main and serious effects of overdosage.

Management:
In such cases it is essential to maintain a patent airway together with assisted ventilation until spontaneous respiration returns.

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.

Shelf life and special precautions for storage

18 months.

Store between 2-8°C. Store in the original container. Do not freeze.

Instructions for use and handling

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Anectine injection may be administered by intravenous infusion as a 0.1% (1mg/ml) or 0.2% (2mg/ml) solution of suxamethonium chloride dihydrate in sterile 5% glucose solution or sterile 0.9% w/v saline solution.

Instructions to open the ampoule:

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

- Hold with the hand the bottom part of the ampoule.
- Put the other hand on the top of the ampoule positioning the thumb above the coloured point and press.