

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Suxamethonium Chloride Injection BP 100mg/2ml.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2ml of solution contains 100mg of suxamethonium chloride BP

3. PHARMACEUTICAL FORM

Clear, colourless, sterile solution, intended for parenteral administration to human beings.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Suxamethonium is a short acting depolarising neuromuscular blocking agent for producing muscular relaxation during anaesthesia. It is 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 muscle contractions associated with pharmacologically or electrically-induced convulsions.

4.2. Posology and Method of Administration

Suxamethonium chloride is usually administered by the intravenous route. It is given intravenously after anaesthesia has been induced and should not be administered to the conscious patient. Assisted respiration is necessary.

The dosage for adults and children is dependent on body weight and the degree of muscular relaxation required. The usual single dose for an adult is in the range of 20 to 100mg intravenously, depending on the patient's body weight and the degree of muscular relaxation required. Infants and younger children are relatively resistant to suxamethonium. A suggested dose for children is in the range of 1 to 2mg/kg body weight, intravenously.

If necessary, the intramuscular route may be used and a dose up to 2.5mg/kg body weight may be given intramuscularly to adults or children to a maximum total of 150mg.

For administration by continuous intravenous infusion, a 0.1 to 0.2% solution may be used and the adult dose ranges from 2 to 5mg per minute.

4.3. Contra-Indications

Suxamethonium causes a transient rise in intra-ocular pressure and therefore it should not be used in the presence of glaucoma, detached retina or open eye injury.

Suxamethonium is contra-indicated in patients with a personal or family history of malignant hyperthermia.

Suxamethonium is contra-indicated in patients with inherited atypical or low serum level of pseudocholinesterase.

Suxamethonium is contra-indicated in situations where a large rise in serum potassium may occur; major injury, severe burns, denervation of muscle (upper or lower motor neurone lesions or a combination of these, e.g. spinal cord injury). The potential for potassium release begins 5 - 15 days after injury and persists for 2 - 3 months with burns and trauma and 3 - 6 months following neurological lesions.

Suxamethonium is contra-indicated in patients with cerebral palsy.

Suxamethonium is contra-indicated in patients who are hypersensitive to the drug.

4.4. Special Warnings and Special Precautions For Use

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

Suxamethonium should not be administered to a patient who is not fully anaesthetised.

Neuromuscular function should be monitored when suxamethonium is being used over a prolonged period. In patients with low levels of plasma cholinesterase or with an abnormal pseudocholinesterase, suxamethonium should be used only with extreme caution and where the benefits of the drug are considered to outweigh the risks.

With prolonged use of suxamethonium, the characteristic depolarizing blockade (Phase I block) may change to one with characteristics of a nondepolarising (Phase II) block, leading to prolonged respiratory depression or apnoea.

It is inadvisable to use suxamethonium in patients with advanced myasthenia gravis, neurological disorders, myotonia or muscular disease. Patients with myasthenic (Eaton-Lambert) syndrome are more sensitive than normal to suxamethonium and the dose should be reduced.

Bradycardia may occur, especially in children or after a second dose in adults, and require administration of atropine.

Cardiac arrhythmias can develop in patients receiving digitalis glycosides who are given suxamethonium.

Suxamethonium should be used with caution in patients who have shown hypersensitivity to any neuromuscular blocking drug.

Hypothermia may prolong neuromuscular blocking action.

4.5. Interaction with other Medicinal Products and other Forms of Interaction

The action of suxamethonium may be prolonged by echothiopate, organophosphorus insecticides, tetrahydroaminoacrine (tacrine), hexaflurenium, acetylcholine inhibitors, antiarrhythmic drugs such as procaine, procainamide, quinidine, beta adrenergic blocking drugs, lignocaine, verapamil, certain non-penicillin antibiotics, trimethaphan, aprotinin, diphenhydramine, promethazine, magnesium salts, quinine, chloroquine, phenelzine, promazine, chlorpromazine, lithium, azathioprine, cytotoxic drugs; oxytocin, oestrogens, high dose steroids and oral contraceptives; specific anticholinesterase agents such as neostigmine, pyridostigmine, phyostigmine, edrophonium; anaesthetic agents and drugs including volatile anaesthetic agents, ketamine, morphine and morphine antagonists, pethidine, pancuronium and propanidid. The action of suxamethonium may also be prolonged by liver disease, cancer, pregnancy, dehydration, electrolyte imbalances and overdosage (due to excessive production of succinylmonocholine).

4.6. Pregnancy and Lactation

Suxamethonium should not be used during pregnancy unless the potential benefits outweigh the possible risks. There is increased sensitivity to suxamethonium during pregnancy and the postpartum period

4.7. Effects on Ability to Drive and Use Machines

Not relevant.

4.8. Undesirable Effects

Muscle pain can occur following the use of suxamethonium. It occurs most frequently in ambulatory patients during the early post-operative period.

Suxamethonium has some muscarinic actions and may cause some increase in bowel movements and in salivary, bronchial and gastric secretions.

Reported side effects include tachycardia, hypertension, hypotension, arrhythmias, bradycardia, prolonged respiratory depression or apnoea, hyperthermia, increased intraocular pressure, muscle fasciculation, myoglobinaemia and hypersensitivity reactions.

4.9 Overdose

Apnoea and prolonged muscle paralysis are the main and serious effects of overdosage. It is essential to maintain the airway and to ensure adequate ventilation until spontaneous respiration occurs. Neostigmine and other anticholinesterase drugs are not antidotes to suxamethonium but would normally intensify the depolarisation effect.

However, in some cases when the action of suxamethonium is prolonged, the characteristic depolarising (Phase I) block may change to one with characteristics of a non-depolarising (Phase II) block. To investigate this possibility, the short-acting anticholinesterase drug, edrophonium, may be given intravenously. If an obvious improvement is maintained for several minutes, neostigmine may be given with atropine. Subsequently, the patient should be observed carefully and if apnoea recurs, a further dose of neostigmine is indicated.

Transfusion of fresh whole blood, frozen plasma, or other source of pseudocholinesterase will help the destruction of suxamethonium.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

A cholinester of succinic acid, the cation formed by the succinic acid radical with the quaternary ammonium group at each end of the molecule is the active part. Deteriorates in hot climates. A depolarising neuromuscular blocking drug of brief duration, its action being prolonged by repeated doses. Its action can be prolonged by various drugs or by a deficiency of cholinesterase due to liver disease or an inherited enzyme deficiency.

It has certain adverse effects ranging from minor to grave consequences. Its beneficial effect is the rapidity in which the airway can be secured by endotracheal intubation.

The contraindications, precautions and warnings are well documented.

5.2. Pharmacokinetic Properties

Following intravenous administration, there is rapid hydrolysis by pseudocholinesterase with the initial metabolite being succinylmonocholine a weak neuro-muscular drug. This is metabolised to succinic acid with only a small amount excreted in the urine.

Only a small fraction of suxamethonium reaches the neuromuscular junction.

Its action is terminated by diffusion away from the end plate.

Succinylcholine does not readily cross the placenta.

5.3. Pre-clinical Safety Data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Sodium Acetate B.P

Water for Injections BP

6.2. Incompatibilities

Suxamethonium should not be mixed in the same syringe with any other agent especially thiopentone.

6.3. Shelf-Life

Unopened : 18 months

6.4. Special Precautions for Storage

Protect from light.
Store at 2 - 8°C.
Do not freeze.

6.5. Nature and Contents of Container

2ml, clear One point cut (OPC) glass ampoules, glass type 1 Ph.Eur. borosilicate glass, packed in cardboard cartons to contain 10 x 2ml ampoules.

6.6. Instructions for Use/Handling

For I.M. and I.V. injection.
Use as directed by the physician.
Keep out of reach of children.
If only part used, discard the remaining solution

7. MARKETING AUTHORISATION HOLDER

Antigen International Ltd.,
Roscrea,
Co. Tipperary,
Ireland.

8. MARKETING AUTHORISATION NUMBER(S)

PL 02848/0140.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

04 September 1990 / 22 August 1996.

10. DATE OF (PARTIAL) REVISION OF TEXT

July 2009