SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

SUCOL

Suxamethonium Chloride Injection B.P.

Strength

100mg/2ml

2. Qualitative and quantitative composition

Sr. No.	Particulars	Grade	Qty. / ml	Function
1.	Suxamethonium chloride	B.P.	50 mg	Active

For Full list of Excipients Refer section 6.1

3. Pharmaceutical form

Liquid Injection

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

Route of administration: For I.M/I.V/I.V Infusion use

Dosage is individualised and its administration should be determined after careful assessment of the patient. The dose of suxamethonium is dependent on bodyweight, the degree of muscle relaxation required and the response of individual patients. Suxamethonium causes paralysis of the respiratory muscles, therefore after administration, respiration must be controlled. It should not be administered to a conscious patient.

Suxamethonium should not be mixed with any neuromuscular blocking agent, nor with general anaesthetics such as short acting barbiturates, nor any other therapeutic agent in the same syringe.

Suxamethonium Chloride Injection contains no antimicrobial agent. It should be used only once and any residue discarded. An initial test dose of 0.1 mg/kg may be given intravenously to determine the patients response.

Adult: For short procedures, such as endotracheal intubation the usual adult dose is 0.6 mg/kg (range 0.3 - 1.1 mg/kg) administered IV over 10 to 30 seconds. This dose produces muscle relaxation in about 60 seconds and has a duration of approximately 4 to 6 minutes. Larger doses produce more prolonged muscle relaxation.

For more prolonged surgical procedures in an adult, suxamethonium is commonly given by IV infusion at a rate of 2.5 - 4.3 mg/minute. When given by intravenous infusion

suxamethonium should be diluted to 0.1 to 0.2% (1 - 2 mg/mL) in 5% dextrose solution or sterile isotonic saline.

Children: Neonates and premature infants may be relatively resistant to suxamethonium. The usual paediatric IV dose is 1 to 2 mg/kg. If necessary, additional doses maybe administered in accordance with patients response. Continuous IV infusions of suxamethonium are considered unsafe in neonates and children because of the risk of inducing malignant hyperthermia.

Intravenous bolus in children may result in profound bradycardia or on occasion asystole. This tends to be more common after a second dose. Pretreatment with atropine can reduce the risk of bradycardia.

When a suitable vein is inaccessible, suxamethonium may occasionally be given by intramuscular injection. A suggested i.m. dose for adults and children may be up to 2.5 mg/kg but the total dose should not exceed 150 mg.

Diluted solutions of suxamethonium must be used within 24 hours of preparation. Discard unused solutions.

4.3 Contraindications

Suxamethonium is contraindicated in persons with personal or familial history of malignant hyperthermia, congenital myotonic disease, Duchenne muscular dystrophy, skeletal muscle myopathies, low plasma- cholinesterase activity (including severe liver disease) and known hypersensitivity to the drug.

It is also contraindicated in patients after the acute phase of injury following major burns, multiple trauma, extensive denervation of skeletal muscle, or upper motor neuron injury which causes prolonged immobilization because suxamethonium administered to such individuals may result in severe hyperkalemia which may result in cardiac arrest. The risk of hyperkalemia in these patients begins 5 - 15 days after injury and persists for 2 – 3 months with burns and trauma and 3 - 6 months following neurological lesions. 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.

4.4 Special warnings and precautions for use

Suxamethonium should only be administered under strict supervision of an anaesthetist familiar with its actions, characteristics and hazards who is skilled in the management of artificial respiration and only when facilities are instantly available for endotracheal intubation and for providing adequate ventilation of the patient, including the administration of oxygen under positive pressure. Be prepared to assist or control respiration. Suxamethonium has no effect on consciousness, pain threshold or cerebration. It should therefore only be used with adequate anaesthesia.

Malignant hyperthermia

The abrupt onset of malignant hyperthermia, a very rare hypermetabolic process of skeletal muscle, may be triggered by suxamethonium. Early premonitory signs include muscle rigidity, tachycardia, tachypnea unresponsive to increased depth of anaesthesia, evidence of increased oxygen requirement and carbon dioxide production, rising temperature and metabolic acidosis.

Hyperkalaemia

Administration of suxamethonium causes an immediate rise in serum potassium.

Great caution should also be observed in patients with pre-existing hyperkalaemia or electrolyte imbalance, uraemia, hemiplegia, paraplegia, extensive burns, massive trauma,

diffuse intracranial lesions (head injury,encephalitis, ruptured cerebral aneurysm), tetanus, acute anterior horn cell disease, extensive denervation of skeletal muscle due to disease or injury of the CNS, or who have degenerative neuromuscular disease and in severe longlasting sepsis. Such patients may become severely hyperkalaemic when given suxamethonium, resulting in cardiac arrhythmia or arrest. With burns or trauma the period of greatest risk is from about 10-90 days after the injury, but may be prolonged further if there is delayed healing or persistent infection. These patients may still react abnormally to suxamethonium 2 years after the injury. In neuromuscular disease the greatest risk period is usually from 3 weeks to 6 months after onset, but severe hyperkalaemia may occur after 24 to 48 hours or later than 6 months. Patients with severe sepsis for more than a week should be considered at risk of hyperkalaemia and suxamethonium should not be given until the infection has cleared.

Hyperkalaemia rhabdomyolysis
There is a risk of cardiac arrest from hyperkalaemia due to rhabdomyolysis, particularly in male patients with muscular dystrophy.

Low plasma pseudocholinesterase
Recovery from suxamethonium may occasionally be delayed possibly due to a low serum pseudocholinesterase level; this may occur in patients suffering from severe liver disease, cancer, malnutrition, severe dehydration, severe anaemia, myxoedema, burns, pregnancy and abnormal body temperature. Suxamethonium should be administered with extreme caution and in reduced doses in such patients. If low pseudocholinesterase concentration is suspected slow administration of a small test dose of suxamethonium (5 to 10 mg as a 0.1% solution) should be considered.

Antidysrhythmic agents
Suxamethonium should be administered with great caution in patients receiving quinidine and who may have digitalis toxicity. In these circumstances the rise in serum potassium due to suxamethonium may possibly cause arrhythmias.

Delayed recovery
When recovery from suxamethonium is delayed, assisted respiration sufficient for full oxygenation, yet avoiding excessive elimination of carbon dioxide, should be maintained until paralysis ceases. This should be combined with light narcoisis, e.g. nitrous oxide/oxygen mixture.

Nondepolarising blockade
If suxamethonium is given repeatedly or over a prolonged period the depolarising block may change to one with characteristics of a nondepolarising block. This may be associated with prolonged respiratory depression and apnoea. Following a positive diagnosis of a nondepolarising blockade the administration of neostigmine preceded by atropine may be considered.

Debilitated patients
Use with caution in patients who are hypoxic or those who have cardiovascular, hepatic, pulmonary, metabolic or renal disorders of myasthenia gravis. The action of suxamethonium may be altered in these patients. Its use is not advisable in patients with phaeochromocytoma. As suxamethonium produces muscle contractions before relaxation it should be used with caution in patients with bone fractures. Suxamethonium should be avoided in patients with myotonias, as response is unpredictable.Use in eye surgery

Suxamethonium causes a slight transient increase in intraocular pressure immediately after injection and during the fasciculation phase. It should therefore be used cautiously if a all during intraocular surgery and in patients with glaucoma.

4.5 Interaction with other medicinal products and other forms of interactions

Drugs which may enhance the neuromuscular blocking action of succinylcholine include: promazine, oxytocin, aprotinin, certain nonpenicillin antibiotics, quinidine, ^{2}-adrenergic blockers, procainamide,lidocaine, trimethaphan, lithium carbonate, magnesium salts, quinine, chloroquine, diethylether, isoflurane, desflurane, metoclopramide, and terbutaline. The neuromuscular blocking effect of succinylcholine may be enhanced by drugs that reduce plasma cholinesterase activity (e.g.,chronically administered oral contraceptives, glucocorticoids, or certain monoamine oxidase inhibitors) or by drugs that irreversibly inhibit plasma cholinesterase. If other neuromuscular blocking agents are to be used during the same procedure, the possibility of a synergistic or antagonistic effect should be considered.

4.6 Pregnancy and lactation

Teratogenic Effects: Pregnancy Category C

Animal reproduction studies have not been conducted with suxamethonium chloride. It is also not known whether suxamethonium can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Suxamethonium should be given to a pregnant woman only if clearly needed.

Non-teratogenic Effects

Plasma cholinesterase levels are decreased by approximately 24% during pregnancy and for several days postpartum. Therefore, a higher proportion of patients may be expected to show increased sensitivity (prolonged apnea) to suxamethonium when pregnant than when non-pregnant.

Labor and Delivery

Suxamethonium is commonly used to provide muscle relaxation during delivery by cesarean section. While small amounts of suxamethonium are known to cross the placental barrier, under normal conditions the quantity of drug that enters fetal circulation after a single dose of 1 mg/kg to the mother should not endanger the fetus. However, since the amount of drug that crosses the placental barrier is dependent on the concentration gradient between the maternal and fetal circulations, residual neuromuscular blockade (apnea and flaccidity) may occur in the neonate after repeated high doses to, or in the presence of atypical plasma cholinesterase in, the mother.

Nursing Mothers

It is not known whether suxamethonium is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised following suxamethonium administration to a nursing woman.

Pediatric Use

There are rare reports of ventricular dysrhythmias and cardiac arrest secondary to acute rhabdomyolysis with hyperkalemia in apparently healthy children who receive suxamethonium (see Warnings). Since it is difficult to identify which patients are at risk, it is recommended that the use of suxamethonium in children should be reserved for emergency intubation or instances where immediate securing of the airway is necessary, e.g., laryngospasm, difficult airway, full stomach, or for intramuscular use when a suitable vein is inaccessible. As in adults, the incidence of bradycardia in children is higher following the second dose of suxamethonium. The incidence and severity of bradycardia is higher in children than in adults. Pretreatment with anticholinergic agents, e.g., atropine, may reduce the occurrence of bradyarrhythmias.

4.7 Effects on ability to drive and operate 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

The following side effects have been reported following administration of suxamethonium:

Neuromuscular: post-operative muscle pain, muscle fasciculation, rhabdomyolysis, myoglobinuria, myoglobinaemia, elevated creatine phosphokinase, hypertonia.

Cardiovascular: bradycardia, tachycardia, arrhythmias, cardiac arrest,hypertension, hypotension, tachyphylaxis, ventricular fibrillation as a result of hyperkalaemia.

Respiratory: apnoea, prolonged respiratory failure, bronchospasm, increased bronchial secretions, pulmonary oedema in infants.

Endocrine, metabolic: malignant hyperthermia, porphyria, hyperkalaemia, excessive salivation.

Gastrointestinal: increased intragastric pressure, increased bowel movements, increased gastric secretions, possible aspiration. Special senses: increased intraocular pressure.

Other: Rise in intracranial pressure, renal failure, precipitation or exacerbation of myasthenia gravis Hypersensitivity reactions including circulatory collapse, flushing, rash, urticaria, bronchospasm and shock, which may lead to death.

4.9 Overdosage

The most serious effects of overdosage are apnoea and prolonged muscle paralysis. It is essential to maintain the airway and adequate ventilation until spontaneous respiration is fully restored.

The use of neostigmine to reverse a nondepolarising block is a clinical decision which depends on the subject, the experience, and the judgment of the clinician. If neostigmine is used, its administration should be accompanied by an appropriate dose of atropine.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: musculo-skeletal system; muscle relaxants, peripherally acting agents; choline derivatives, ATC code: M03AB01

Suxamethonium is an ultra-short acting depolarising, neuromuscular blocking substance. Suxamethonium is closely related in structure to acetylcholine. Similar to acetylcholine, suxamethonium acts on the skeletal muscle motor endplate, to cause flaccid paralysis (Phase I block). Suxamethonium diffuses slowly to the endplate and the concentration at the endplate persists for long enough to cause loss of electrical excitability. The depolarisation of the muscle endplate establishes a voltage gradient and this causes opening of voltage-dependent ion channels of the muscle leading to transient contraction of the muscle. Although the end-plate stays depolarised, the muscle membrane accounts for this depolarization and remains flaccid. If suxamethonium is continuously infused, the junctional membrane slowly regains its resting potential with the return of neuromuscular transmission(tachyphylaxis); hence to maintain the effect, a higher infusion rate is required. With continued infusion, neuromuscular transmission will fail

again (Phase II block) even though the membrane potential of the end-plate stays relatively unchanged. A Phase II block has the clinical characteristics of a non-depolarising block. A Phase II block may be associated with prolonged neuromuscular blockade and apnoea. The mechanism of this block is not known but channel Health Products Regulatory Authority 24 April 2020 CRN008LKR Page 8 of 10 blocking by penetration of suxamethonium into the sub-end plate cytoplasm, intracellular accumulation of calcium and sodium, the loss of intracellular potassium, and activation of Na,K-ATPase all contribute. The short duration of action of suxamethonium is considered to be due to its rapid metabolism in the blood. Suxamethonium is rapidly hydrolysed by plasma cholinesterase to succinylmonocholine which possesses clinically insignificant depolarising muscle relaxant properties.

5.2 Pharmacokinetic properties

Absorption: Suxamethonium has a rapid onset and a short duration of action. Following intravenous (IV) administration of a single therapeutic dose in healthy adults, complete muscle relaxation occurs within 1/2 to 1 minute, persists for about 2 - 3 minutes, and gradually dissipates within 10 minutes.

Following intramuscular (IM) administration the onset of action occurs in about 2 - 3 minutes, with a duration ranging from 10 - 30 minutes.

The duration of action is prolonged in patients with low plasma pseudocholinesterase concentration.

Distribution: Suxamethonium crosses the placenta, generally in small amounts.

Elimination: Plasma pseudocholinesterases hydrolyse suxamethonium to succinylmonocholine (relatively inactive) and choline. Approximately 10% of drug is excreted unchanged in the urine. Patients with impaired renal function may occasionally experience prolonged apnoea due to accumulation of succinylmonocholine.

5.3 Pre-clinical Safety Data

There is no pre-clinical data of relevance to the prescriber which is additional to that already included in other sections of the Summary of Products Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Benzyl Alcohol B.P.
Water for Injections B.P.

6.2 Incompatibilities

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

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Storage between 2° to 8° C., Do not freeze.

6.5 Nature and contents of container

2 ml amber coloured ampoule with black band snap off

6.6 Special Precautions for Handling and Disposal

Use as directed by a physician.

7. Marketing authorization holder:

M/s. NEON LABORATORIES LIMITED
140, Damji Shamji Industrial Complex,
28, Mahal Industrial Estate, M. Caves Road,
Andheri (E), Mumbai – 400 093.
INDIA

8. Marketing Authorization Number (s):

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9. Date of first authorization/ Renewal of the authorization:

Date of first authorization : 12/11/2018

10. Date of revision of the text:

July 2023

11. References :

Suxamethonium chloride 50mg/ml- Solution for Injection - Summary of Product Characteristics (SmPC) https://www.medicines.org.uk/emc/product/smpc