A short-acting depolarizing skeletal muscle relaxant

Piramal Critical Care

Succinylcholine Chloride Injection, USP

Piramal's Succinylcholine Chloride Injection, USP is available through the wholesaler or distributor of your choice

Wholesaler / Distributor Name	25 Multiple-Dose Vials in a carton: NDC - 66794-232-42 Succinylcholine Chloride Injection, USP (10 mL per vial) Catalog numbers
AmerisourceBergen	10254037
Cardinal	5702063
McKesson	3694650
Morris & Dickson	981506

Succinylcholine Chloride Injection, USP

ABBREVIATED PRESCRIBING INFORMATION

PRODUCT NAME AND COMPOSITION: Succinylcholine Chloride Injection, USP is a short-acting depolarizing skeletal muscle relaxant and is supplied as a clear, colorless solution. Succinylcholine Chloride Injection, USP is a sterile, non-pyrogenic solution to be used as an ultra-short-acting, depolarizing, skeletal muscle relaxant

Please refer to Full Prescribing Information (FPI) before prescribing.

INDICATIONS: Succinylcholine chloride is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

DOSAGE AND ADMINISTRATION: *See FPI for full details*. The average dose required to produce neuromuscular blockade and to facilitate tracheal intubation is 0.6 mg/kg succinylcholine chloride injection given intravenously. The optimum dose will vary among individuals and may be from 0.3 to 1.1 mg/kg for adults. Following administration of doses in this range, neuromuscular blockade develops in about 1 minute; maximum blockade may persist for about 2 minutes, after which recovery takes place within 4 to 6 minutes. However, very large doses may result in more prolonged blockade. A 5 to 10 mg test dose may be used to determine the sensitivity of the patient and the individual recovery time. The average rate for an adult ranges between 2.5 and 4.3 mg per minute. The intravenous dose of succinylcholine is 2 mg/kg for infants and small pediatric patients; for older pediatric patients and adolescents the dose is 1 mg/kg.

CONTRAINDICATIONS: Succinylcholine is contraindicated in persons with personal or familial history of malignant hyperthermia, skeletal muscle myopathies 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, because succinylcholine administered to such individuals may result in severe hyperkalemia which may result in cardiac arrest. The risk of hyperkalemia in these patients increases over time and usually peaks at 7 to 10 days after the injury. The risk is dependent on the extent and location of the injury.

COMMON SIDE EFFECTS: Succinylcholine causes profound muscle relaxation resulting in respiratory depression to the point of apnea; this effect may be prolonged. Hypersensitivity reactions, including anaphylaxis, may occur in rare instances. The following additional adverse reactions have been reported: cardiac arrest, malignant hyperthermia, arrhythmias, bradycardia, tachycardia, hypertension, hypotension, hyperkalemia, prolonged respiratory depression or apnea, increased intraocular pressure, muscle fasciculation, jaw rigidity, postoperative muscle pain, and rhabdomyolysis with possible myoglobinuric acute renal failure, excessive salivation, and rash.

See FPI for a complete list.

WARNINGS AND PRECAUTIONS: There have been rare reports of acute rhabdomyolysis with hyperkalemia followed by ventricular dysrhythmias, cardiac arrest and death after the administration of succinylcholine to apparently healthy pediatric patients who are subsequently found to have

undiagnosed skeletal muscle myopathy, most frequently Duchenne's muscular dystrophy. This syndrome often presents as peaked T-waves and sudden cardiac arrest within minutes after the administration of the drug in healthy appearing pediatric patients (usually, but not exclusively, males, and most frequently 8 years of age or younger). There have also been reports in adolescents. Therefore, when a healthy appearing infant or child develops cardiac arrest soon after administration of succinylcholine, not felt to be due to inadequate ventilation, oxygenation or anesthetic overdose, immediate treatment for hyperkalemia is instituted. This should include administration of intravenous calcium, bicarbonate, and glucose with insulin, with hyperventilation. Due to the abrupt onset of this syndrome, routine resuscitative measures are likely to be unsuccessful. However, extraordinary and prolonged resuscitative efforts have resulted in successful resuscitation in some reported cases. In addition, in the presence of signs of malignant hyperthermia, appropriate treatment is instituted concurrently. Since there may be no signs or symptoms to alert the practitioner to which patients are at risk, it is recommended that the use of succinylcholine in pediatric patients 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.

When succinylcholine given is over a prolonged period, the characteristic depolarization block of the myoneural junction (Phase I block) may change to a block with characteristics superficially resembling a non-depolarizing block (Phase II block). Prolonged respiratory muscle paralysis or weakness is observed in patients manifesting this transition to Phase II block. The transition from Phase I to Phase II block has been reported in 7 of 7 patients studied under halothane anesthesia after an accumulated dose of 2 to 4 mg/kg succinylcholine (administered in repeated, divided doses). The onset of Phase II block coincided with the onset of tachyphylaxis and prolongation of spontaneous recovery. In another study, using balanced anesthesia (N_2O/O_2/narcotic-thiopental) and succinylcholine infusion, the transition was less abrupt, with great individual variability in the dose of succinylcholine required to produce Phase II block. Of 32 patients studied, 24 developed Phase II block. Tachyphylaxis was not associated with the transition to Phase II block, and 50% of the patients who developed Phase II block experienced prolonged recovery. When Phase II block is suspected in cases of prolonged neuromuscular blockade, positive diagnosis should be made by peripheral nerve stimulation, prior to administration of any anticholinesterase drug. Reversal of Phase II block is a medical decision, which must be made upon the basis of the individual, clinical pharmacology and the experience and judgment of the physician. The presence of Phase II block is indicated by fade of responses to successive stimuli (preferably "train of four"). The use of an anticholinesterase drug to reverse Phase II block should be accompanied by appropriate doses of an anticholinergic drug to prevent disturbances of cardiac rhythm. After adequate reversal of Phase II block with an anticholinesterase agent, the patient should be continually observed for at least 1 hour for signs of return of muscle relaxation. Reversal should not be attempted unless: (1) a peripheral nerve stimulator is used to determine the presence of Phase II block (since anticholinesterase agents will potentiate succinylcholine-induced Phase I block), and (2) spontaneous recovery of muscle twitch has been observed for at least 20 minutes and has reached a plateau with further recovery proceeding slowly; this delay is to ensure complete hydrolysis of succinylcholine by plasma cholinesterase prior to administration of the anticholinesterase agent. Should the type of block be misdiagnosed, an anticholinesterase agent will prolong depolarization of the type initially induced by succinylcholine (i.e., Phase I block).

See FPI for full details.

OVERDOSAGE: Overdosage with succinylcholine may result in neuromuscular block beyond the time needed for surgery and anesthesia. This maybe manifested by skeletal muscle weakness, decreased respiratory reserve, low tidal volume, or apnea. The primary treatment is maintenance of a patent airway and respiratory support until recovery of normal respiration is assured. Depending on the dose and duration of succinylcholine administration, the characteristic depolarizing neuromuscular block (Phase I) may change to a block with characteristics superficially resembling a non-depolarizing block (Phase II).

For more information, please contact Piramal Customer Service at +1-800-414-1901 during business hours (8 a.m. EST to 5 p.m. EST) or e-mail at pcc.customerservice@piramal.com

- Full prescribing information of Succinylcholine Chloride Injection, USP can be seen at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b94ff0a2-a770-47a6-e053-2995a90a7fbc.
- Adverse events should be reported to Piramal Critical Care at http://pcc-chex.force.com/SiteComplaintForm.
- You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

"Saving and Improving Patients' Lives."

Piramal Critical Care

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