



# Succinylcholine Chloride Injection, USP

Succinylcholine should be employed with caution in patients with fractures or muscle spasm because the initial muscle fasciculations may cause additional trauma.

Succinylcholine may cause a transient increase in intracranial pressure; however, adequate anesthetic induction prior to administration of succinylcholine will minimize this effect. Succinylcholine may increase intragastric pressure, which could result in regurgitation and possible aspiration of stomach contents. Neuromuscular blockade may be prolonged in patients with hypokalemia or hypocalcemia. Since allergic cross-reactivity has been reported in this class, request information from your patients about previous anaphylactic reactions to other neuromuscular blocking agents. In addition, inform your patients that severe anaphylactic reactions to neuromuscular blocking agents, including succinylcholine have been reported.

Reduced Plasma Cholinesterase Activity

Succinylcholine should be used carefully in patients with reduced plasma cholinesterase (pseudocholinesterase) activity. The likelihood of prolonged neuromuscular block following administration of succinylcholine must be considered in such patients (see **DOSEAGE AND ADMINISTRATION**).

Plasma cholinesterase activity may be diminished in the presence of genetic abnormalities of plasma cholinesterase (e.g., patients heterozygous or homozygous for atypical plasma cholinesterase gene), pregnancy, severe liver or kidney disease, malignant tumors, infections, burns, anemia, decompensated heart disease, peptic ulcer, or myxedema. Plasma cholinesterase activity may also be diminished by chronic administration of oral contraceptives, glucocorticoids, or certain monoamine oxidase inhibitors and by irreversible inhibitors of plasma cholinesterase (e.g., organophosphate insecticides, echthiophate, and certain antineoplastic drugs).

Patients homozygous for atypical plasma cholinesterase gene (1 in 2500 patients) are extremely sensitive to the neuromuscular blocking effect of succinylcholine. In these patients, a 5 to 10 mg test dose of succinylcholine may be administered to evaluate sensitivity to succinylcholine, or neuromuscular blockade may be produced by the cautious administration of a 1 mg/mL solution of succinylcholine by slow intravenous infusion. Apnea or prolonged muscle paralysis should be treated with controlled respiration.

Drug Interactions

Drugs which may enhance the neuromuscular blocking action of succinylcholine include: promazine, oxytocin, aprotinin, certain non-penicillin antibiotics, quinidine, β-adrenergic blockers, procainamide, lidocaine, trimethaphan, lithium carbonate, magnesium salts, quinine, chloroquine, diethyl ether, 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 (see **PRECAUTIONS**).

If other neuromuscular blocking agents are to be used during the same procedure, the possibility of a synergistic or antagonistic effect should be considered.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There have been no long-term studies performed in animals to evaluate carcinogenic potential of succinylcholine. Genetic toxicology studies have not been completed to evaluate the genotoxic potential of succinylcholine. There are no studies to evaluate the potential impact of succinylcholine on fertility.

Pregnancy

Risk Summary

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

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

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 succinylcholine when pregnant than when nonpregnant.

Labor and Delivery

Succinylcholine is commonly used to provide muscle relaxation during delivery by caesarean section. While small amounts of succinylcholine 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 newborn after repeated high doses to, or in the presence of atypical plasma cholinesterase in, the mother.

Nursing Mothers

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

Pediatric Use

Safety and effectiveness of succinylcholine chloride have been established in pediatric patient age groups, neonate to adolescent. There are rare reports of ventricular dysrhythmias and cardiac arrest secondary to acute rhabdomyolysis with hyperkalemia in apparently healthy pediatric patients who receive succinylcholine (see **BOX WARNING**). Many of these pediatric patients were subsequently found to have a skeletal muscle myopathy such as Duchenne's muscular dystrophy whose clinical signs were not obvious. The syndrome often presents as sudden cardiac arrest within minutes after the administration of succinylcholine. These pediatric patients are usually, but not exclusively, males, and most frequently 8 years of age or younger. There have also been reports in adolescents. There may be no signs or symptoms to alert the practitioner to which patients are at risk. A careful history and physical may identify developmental delays suggestive of a myopathy. A preoperative creatine kinase could identify some but not all patients at risk. Due to the abrupt onset of this syndrome, routine resuscitative measures are likely to be unsuccessful. Careful monitoring of the electrocardiogram may alert the practitioner to peaked T-waves (an early sign). Administration of intravenous calcium, bicarbonate, and glucose with insulin, with hyperventilation have resulted in successful resuscitation in some of the reported cases. Extraordinary and prolonged resuscitative efforts have been effective in some cases. In addition, in the presence of signs of malignant hyperthermia, appropriate treatment should be initiated concurrently (see **WARNINGS**). Since it is difficult to identify 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.

As in adults, the incidence of bradycardia in pediatric patients is higher following the second dose of succinylcholine. The incidence and severity of bradycardia is higher in pediatric patients than adults. Pre-treatment with anticholinergic agents, e.g., atropine, may reduce the occurrence of bradyarrhythmias.

Geriatric Use

Clinical studies of Succinylcholine Chloride Injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

Adverse reactions to succinylcholine consist primarily of an extension of its pharmacological actions. 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, rhabdomyolysis with possible myoglobinuric acute renal failure, excessive salivation, and rash.

There have been post-marketing reports of severe allergic reactions (anaphylactic and anaphylactoid reactions) associated with use of neuromuscular blocking agents, including succinylcholine. These reactions, in some cases, have been life threatening and fatal. Because these reactions were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency (see **WARNINGS** and **PRECAUTIONS**).

OVERDOSAGE

Overdosage with succinylcholine may result in neuromuscular block beyond the time needed for surgery and anesthesia. This may be 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) (see **PRECAUTIONS**).

DOSEAGE AND ADMINISTRATION

The dosage of succinylcholine should be individualized and should always be determined by the clinician after careful assessment of the patient (see **WARNINGS**).

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Solutions which are not clear and colorless should not be used.

Succinylcholine is for intravenous or intramuscular use only.

Succinylcholine must be titrated to effect by or under supervision of experienced clinicians who are familiar with its actions and with appropriate neuromuscular monitoring techniques.

Succinylcholine should be administered only by those skilled in the management of artificial respiration and only when facilities are instantly available for tracheal intubation and for providing adequate ventilation of the patient, including the administration of oxygen under positive pressure and the elimination of CO2. The clinician must be prepared to assist or control respiration.

To avoid distress to the patient, do not administer Succinylcholine before unconsciousness has been induced (see **WARNINGS**).

The occurrence of bradyarrhythmias with administration of Succinylcholine may be reduced by pretreatment with anticholinergics (e.g., atropine) (see **WARNINGS**).

Monitor neuromuscular function with a peripheral nerve stimulator when using Succinylcholine by infusion (see **PRECAUTIONS**).

Succinylcholine supplied in single-dose vials must be diluted before use. Succinylcholine supplied in multiple-dose vials does not require dilution before use (see **DOSEAGE AND ADMINISTRATION**).

Risk of Medication Errors

Accidental administration of neuromuscular blocking agents may be fatal. Store Succinylcholine Chloride Injection with the cap and ferrule intact and in a manner that minimizes the possibility of selecting the wrong product.

Adults

For Short Surgical Procedures

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 (see **PRECAUTIONS**).

For Long Surgical Procedures

The dose of succinylcholine administered by infusion depends upon the duration of the surgical procedure and the need for muscle relaxation. The average rate for an adult ranges between 2.5 and 4.3 mg per minute.

Solutions containing from 1 to 2 mg per mL succinylcholine have commonly been used for continuous infusion. The more dilute solution (1 mg per mL) is probably preferable from the standpoint of ease of control of the rate of administration of the drug and, hence, of relaxation. This intravenous solution containing 1 mg per mL may be administered at a rate of 0.5 mg (0.5 mL) to 10 mg (10 mL) per minute to obtain the required amount of relaxation. The amount required per minute will depend upon the individual response as well as the degree of relaxation required. Avoid overburdening the circulation with a large volume of fluid. It is recommended that neuromuscular function be carefully monitored with a peripheral nerve stimulator when using succinylcholine by infusion in order to avoid overdose, detect development of Phase II block, follow its rate of recovery, and assess the effects of reversing agents (see **PRECAUTIONS**).

Intermittent intravenous injections of succinylcholine may also be used to provide muscle relaxation for long procedures. An intravenous injection of 0.3 to 1.1 mg/kg may be given initially, followed, at appropriate intervals, by further injections of 0.04 to 0.07 mg/kg to maintain the degree of relaxation required.

Pediatrics

For emergency tracheal intubation or in instances where immediate securing of the airway is necessary, 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 (see **BOX WARNING** and **PRECAUTIONS: Pediatric Use**). It is currently known that the effective dose of succinylcholine in pediatric patients may be higher than that predicted by body weight dosing alone. For example, the usual adult IV dose of 0.6 mg/kg is comparable to a dose of 2-3 mg/kg in neonates and infants to 6 months and 1-2 mg/kg in infants up to 2 years of age. This is thought to be due to the relatively large volume of distribution in the pediatric patient versus the adult patient.

Rarely, IV bolus administration of succinylcholine in infants and pediatric patients may result in malignant ventricular arrhythmias and cardiac arrest secondary to acute rhabdomyolysis with hyperkalemia. In such situations, an underlying myopathy should be suspected.

Intravenous bolus administration of succinylcholine in infants or pediatric patients may result in profound bradycardia or, rarely, asystole. As in adults, the incidence of bradycardia in pediatric patients is higher following a second dose of succinylcholine. Whereas bradycardia is common in pediatric patients after an initial dose of 1.5 mg/kg, bradycardia is seen in adults only after repeated exposure. The occurrence of bradyarrhythmias may be reduced by pretreatment with atropine (see **PRECAUTIONS: Pediatric Use**).

Intramuscular Use

If necessary, succinylcholine may be given intramuscularly to infants, older pediatric patients or adults when a suitable vein is inaccessible. A dose of up to 3 to 4 mg/kg may be given, but not more than 150 mg total dose should be administered by this route. The onset of effect of succinylcholine given intramuscularly is usually observed in about 2 to 3 minutes.

Compatibility and Admixtures

Succinylcholine is acidic (pH 3.5) and should not be mixed with alkaline solutions having a pH greater than 8.5 (e.g., barbiturate solutions). Admixtures containing 1 to 2 mg/mL may be prepared by adding 1 g Succinylcholine Chloride Injection to 1,000 or 500 mL sterile solution, such as 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP. Admixtures of Succinylcholine Chloride Injection must be used within 24 hours after preparation. Aseptic techniques should be used to prepare the diluted product. Admixtures of Succinylcholine Chloride Injection should be prepared for single patient use only. The unused portion of diluted Succinylcholine Chloride Injection should be discarded.

To prevent needle-stick injuries, needles should not be recapped, purposely bent, or broken by hand.

HOW SUPPLIED

Succinylcholine Chloride Injection, USP is supplied as a clear, colorless solution in the following concentration and package:

NDC No.	Container	Size (mL)	mg/mL	mg (Total)	mOsmol/mL (calc.)
Multiple Dose 14789-104-05	Fliptop Vial	10	20	200 mg	0.338

Refrigeration of the undiluted agent will assure full potency until expiration date. All units carry a date of expiration.

The container closure is not made with natural rubber latex.

**Store in refrigerator 2° to 8°C (36° to 46°F).** The multi-dose vials are stable for up to 14 days at room temperature without significant loss of potency.

Manufactured in Germany for:  
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