November 5, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned petitioner submits this petition, on behalf of a client, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FD&C Act"), and in accordance with 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30 requesting the Commissioner of the Food and Drug Administration ("FDA") to declare that the proposed drug products, Succinylcholine Chloride Injection 100 mg/5 mL (20 mg/mL) and 200 mg/10 mL (20 mg/mL) in single dose Prefilled Syringe presentations are suitable for consideration in an Abbreviated New Drug Application ("ANDA").

I. ACTION REQUESTED

The petitioner requests that the Commissioner of the FDA declare that the proposed drug products, Succinylcholine Chloride Injection, 100 mg/5 mL (20 mg/mL) and 200 mg/10 mL (20 mg/mL) single dose Prefilled Syringes (PFS) are suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based, is QUELICIN® (Succinylcholine Chloride) Injection, 200 mg/10 mL (20 mg/mL) multiple-dose vials by Hospira NDA # 008845, Product Number 006.

The petitioner, hereby, seeks a change in strength from 200 mg/10 mL multiple-dose vial to 100 mg/5 mL (as an additional strength) in a single dose Prefilled Syringe presentation. It should be noted that the change in strength is only a change in the total drug content and not in concentration.

The petitioner also seeks change in the container closure system for the currently approved strength of 200 mg/10 mL (multiple-dose vial to single dose Prefilled Syringe).

II. STATEMENT OF GROUNDS

The FD&C Act § 505(j)(2)(A) provides for the submission of an ANDA for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

Furthermore, pursuant to Section 505(j) of the FD&C Act, the ANDA for a proposed drug product is not obligated to use the same container closure system as the one used by the applicant of the RLD. However, the ANDA is required to provide appropriate information to ensure that the proposed drug product has the same conditions of use and the same labeling as the RLD pursuant to Section 505(j)(2)(A)(v) of the FD&C Act.

The RLD for the proposed drug product, QUELICIN® Injection by HOSPIRA is an injection product containing Succinylcholine Chloride, 200 mg /10 mL (20 mg/mL) as a multiple-dose vial. A copy of the relevant excerpt from the current electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* is provided as **Attachment 1**. A copy of the current labeling for QUELICIN® Injection by HOSPIRA is provided as **Attachment 2**.

- This petition is seeking a change in strength (total drug content) and proposes a new strength of 100 mg/5 mL (20 mg/mL) in a single dose Prefilled Syringe presentation. Note that the change in strength is only a change in the total drug content and not in concentration.

- This petition is also seeking a change in container closure system for the currently approved 200 mg/10 mL (20 mg/mL) strength and proposes to provide a single dose Prefilled Syringe presentation in place of multiple-dose vial.

The same is tabulated as below:

Currently available as	**Proposed Drug Product I (proposing change in strength, proposing new container closure system)**	**Proposed Drug Product II (proposing change in container closure system)**
QUELICIN 200 mg/10mL (20 mg/mL)- RLD	Succinylcholine Chloride Injection 100 mg/5 mL (20 mg/mL)	Succinylcholine Chloride Injection 200 mg/10 mL (20 mg/mL)
Container Closure System: Multiple-dose Vial	**Proposed Container Closure System:** Single-dose Prefilled Syringe	**Proposed Container Closure System:** Single-dose Prefilled Syringe

There are no proposed changes in labeling, with the exception of the obvious changes in strength and the change in the container closure system, sought in this petition. The active ingredient, dosage form and route of administration, as well as the uses, indications, warnings, and directions for use will remain the same as that of the RLD. The draft *Package Insert* incorporating the proposed additional strength as well as the proposed contain closure system is provided in **Attachment 3.**

The proposed change in the strength represents dosage strengths that are clearly contemplated in the labeling of the RLD, QUELICIN®. According to the Dosage and Administration in the current approved *Package Insert* for QUELICIN®:

> ***DOSAGE 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.
>
> **Risk of Medication Errors**
> Accidental administration of neuromuscular blocking agents may be fatal. Store QUELICIN 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 QUELICIN 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***).

As indicated in the Dosage and Administration section of the *Package Insert* for QUELICIN®, when a 20 mg/mL, 10mL multiple-dose vial of Succinylcholine Chloride (200mg/10mL) is dosed to patients for short surgical procedures, the average dose required to produce neuromuscular blockade and to facilitate tracheal intubation is 0.6 mg/kg Succinylcholine Chloride (200mg/10mL) Injection given intravenously, and that the optimum dose will vary among individuals and may be from 0.3 to 1.1 mg/kg for adults. Thus, for example, a patient having a body weight of 80kg would require an optimum dose of 1.2-4.4 mL (24–88 mg) of Succinylcholine Chloride 20mg/mL product, and a patient having a body weight of 90kg would require an optimum dose of 1.35-4.95 mL (27-99 mg) of Succinylcholine Chloride 20mg/mL product.

The proposed 100mg/5mL (20mg/mL) single dose Prefilled Syringe is, therefore, appropriate for use for such dosing in short surgical procedures.

Further, 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. Due to its rapid onset and short mechanism of action, it is the drug of choice in emergencies where immediate airway management is required. The petitioner is of the opinion that the following reasons further justify the benefits of the 5 mL and 10 mL Prefilled Syringe presentations, especially for an emergency use drug such as Succinylcholine Chloride:

Accessibility: The Prefilled Syringes allow for quick access in emergency situations where intubation is required.

Storage: Prefilled Syringes are easily stored and ready to be administered.

Overdose: The Prefilled Syringes reduce the possibility of overdose.

Single Unit Dosing: The Prefilled Syringes allow for single unit use.

Medication Error: The Prefilled Syringes reduce the possibility of accidental administration errors of neuromuscular blocking agents, such as Succinylcholine, which may be fatal.

Individualized dosing: The dosage of Succinylcholine is required by the label to be individualized and should always be determined by the clinician after careful assessment of the patient. The Prefilled Syringes allow for that unlike Vials.

Expanded route of Administration: The Prefilled Syringes allow for other routes of administration including intramuscular as recommended for infants on the current available *Prescribing Information.*

Contamination: The Prefilled Syringes reduce the possibility of contamination and transmission of infection from one patient to another.

Safety: The Prefilled Syringes make injections easier and safer for both doctors and patients.

Dosing: The Prefilled Syringes would provide a ready to administer preparation which more closely matches calculated dose ranges of Succinylcholine Chloride. With a Prefilled Syringe of Succinylcholine, a patient would consistently receive the right dosage.

Cost to the patient: In addition, pharmaceutical companies can benefit from less overfill in the Prefilled Syringes (compared to vials)—which is an important advantage, particularly with overall cost.

Indeed, the above benefits have resulted in several drug compounding outsourcing facilities registered under Section 503B of the FD&C Act, to manufacture and supply these presentations to Hospitals to meet a requirement for these presentations in the hospitals. List of some of such compounding outsourcing facilities along with their available presentations is provided in **Attachment 4**.

In view of the aforesaid, the petitioner's request for the Commissioner to find that a change in strength as proposed in the form of a new strength of 100 mg/5mL in single dose Prefilled Syringe presentation for Succinylcholine Chloride Injection and a change in the container closure system (from multiple-dose vial to single dose Prefilled Syringe for the currently approved 200 mg/10mL strength) should raise no questions of safety and effectiveness, and the Agency is thereby requested to approve the petition.

C. Inapplicability of the Pediatric Research Equity Act ("PREA")

PREA, which is codified at FD&C Act§ 505B, does not apply to a new strength and a new packaging configuration, such as the one proposed in this petition. As such, PREA should not serve as an impediment to the Agency's granting of this petition.

D. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

E. Economic Impact

The petitioner does not believe that this is applicable in this case but will agree to provide such an analysis if requested by the Agency.

F. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

Michelle R. Ryder
cn=Michelle R. Ryder, o=Lachman Consultant Services, Inc., ou, email=m.ryder@lachmanconsultants.com, c=US
2020.11.05 08:50:10 -07'00'

Michelle R. Ryder
Principal Consultant
Lachman Consulting Services, Inc.

Attachments:

- ATTACHMENT 1: Copy of the relevant excerpt from the current electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations.*

- ATTACHMENT 2: Current labeling for QUELICIN® Injection by HOSPIRA (July 2018 version, source: Drugs@FDA)

- ATTACHMENT 3: Draft Package Insert Proposed for Succinylcholine Chloride Injection incorporating the proposed additional strength as well as the proposed contain closure system.

- ATTACHMENT 4: Examples of 5mL and 10mL single dose Prefilled Syringes for Succinylcholine Chloride Injection 20mg/ml, available through drug *compounding* outsourcing facilities registered under Section *503B o*f the FD&C Act.

ATTACHMENT 1

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search Results for Proprietary Name, Active Ingredient or Application Number: SUCCINYLCHOLINE

Top of Form

☑ RX ☑ OTC ☑ DISCN

Bottom of Form

CSVExcelPrint

Display records per page

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Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	SUCCINYLCHOLINE CHLORIDE	ANECTINE	N008453	INJECTABLE	INJECTION	20MG/ML	AP	RLD	RS	SANDOZ INC
RX	SUCCINYLCHOLINE CHLORIDE	QUELICIN	N008845	INJECTABLE	INJECTION	20MG/ML	AP	RLD	RS	HOSPIRA INC
DISCN	SUCCINYLCHOLINE CHLORIDE	QUELICIN PRESERVATIVE FREE	N008845	INJECTABLE	INJECTION	20MG/ML		RLD		HOSPIRA INC

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	SUCCINYLCHOLINE CHLORIDE	QUELICIN PRESERVATIVE FREE	N008845	INJECTABLE	INJECTION	50MG/ML		RLD		HOSPIRA INC
DISCN	SUCCINYLCHOLINE CHLORIDE	QUELICIN PRESERVATIVE FREE	N008845	INJECTABLE	INJECTION	100MG/ML		RLD		HOSPIRA INC
DISCN	SUCCINYLCHOLINE CHLORIDE	SUCOSTRIN	N008847	INJECTABLE	INJECTION	20MG/ML		RLD		APOTHECON INC DIV BRISTOL MYERS SQUIBB
DISCN	SUCCINYLCHOLINE CHLORIDE	SUCOSTRIN	N008847	INJECTABLE	INJECTION	100MG/ML		RLD		APOTHECON INC DIV BRISTOL MYERS SQUIBB
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A213705	INJECTABLE	INJECTION	20MG/ML	AP			ACCORD HEALTHCARE INC
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A211432	INJECTABLE	INJECTION	20MG/ML	AP			AMNEAL EU LTD
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A213432	INJECTABLE	INJECTION	20MG/ML	AP			AMPHASTAR PHARMACEUTICALS INC
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A210231	INJECTABLE	INJECTION	20MG/ML	AP			AMRING PHARMACEUTICALS INC
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A213810	INJECTABLE	INJECTION	20MG/ML	AP			ASPIRO PHARMA LTD

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A212638	INJECTABLE	INJECTION	20MG/ML	AP			BRECKENRIDGE PHARMACEUTICAL INC
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A210698	INJECTABLE	INJECTION	20MG/ML	AP			DR REDDYS LABORATORIES LTD
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A214246	INJECTABLE	INJECTION	20MG/ML	AP			GLAND PHARMA LTD
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A213229	INJECTABLE	INJECTION	20MG/ML	AP			HIKMA PHARMACEUTICALS INTERNATIONAL LTD
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A214308	INJECTABLE	INJECTION	20MG/ML	AP			INDOCO REMEDIES LTD
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A213552	INJECTABLE	INJECTION	20MG/ML	AP			NEXUS PHARMACEUTICALS INC
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A211625	INJECTABLE	INJECTION	20MG/ML	AP			NIVAGEN PHARMACEUTICALS INC
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A211589	INJECTABLE	INJECTION	20MG/ML	AP			SOMERSET THERAPEUTICS LLC
RX	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A209467	INJECTABLE	INJECTION	20MG/ML	AP		RS	ZYDUS PHARMACEUTICALS USA INC

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
DISCN	SUCCINYLCHOLINE CHLORIDE	ANECTINE	N008453	INJECTABLE	INJECTION	50MG/ML				SANDOZ INC
DISCN	SUCCINYLCHOLINE CHLORIDE	ANECTINE	N008453	INJECTABLE	INJECTION	500MG/VIAL				SANDOZ INC
DISCN	SUCCINYLCHOLINE CHLORIDE	ANECTINE	N008453	INJECTABLE	INJECTION	1GM/VIAL				SANDOZ INC
DISCN	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A080997	INJECTABLE	INJECTION	20MG/ML				ORGANON USA INC
DISCN	SUCCINYLCHOLINE CHLORIDE	SUCCINYLCHOLINE CHLORIDE	A085400	INJECTABLE	INJECTION	100MG/VIAL				INTERNATIONAL MEDICATION SYSTEMS LTD

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ATTACHMENT 2

QUELICIN™
(Succinylcholine Chloride Injection, USP)

A short-acting depolarizing skeletal muscle relaxant.

WARNING
RISK OF CARDIAC ARREST FROM HYPERKALEMIC RHABDOMYOLYSIS

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 were 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 should be 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 should be 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 (see ***PRECAUTIONS***: **Pediatric Use** and ***DOSAGE AND ADMINISTRATION***).

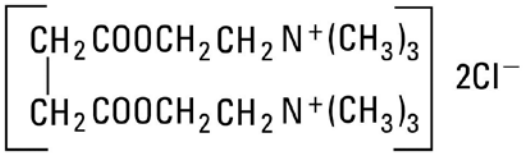
This drug should be used only by individuals familiar with its actions, characteristics and hazards.

DESCRIPTION

QUELICIN (Succinylcholine Chloride Injection, USP) is a sterile, nonpyrogenic solution to be used as an ultra short-acting, depolarizing, skeletal muscle relaxant See ***HOW SUPPLIED*** for summary of content and characteristics of the solutions. The solutions are for intramuscular (IM) or intravenous (IV) use.

Succinylcholine Chloride, USP is chemically designated $C_{14}H_{30}Cl_2N_2O_4$ and its molecular weight is 361.31.

It has the following structural formula:



Succinylcholine is a diquaternary base consisting of the dichloride salt of the dicholine ester of succinic acid. It is a white, odorless, slightly bitter powder, very soluble in water. The drug is incompatible with alkaline solutions but relatively stable in acid solutions. Solutions of the drug lose potency unless refrigerated.

Solution intended for multiple-dose administration contains 0.18% methylparaben and 0.02% propylparaben as preservatives (List No. 6629). Solution intended for single-dose administration contains no preservatives. Unused solution should be discarded. Product not requiring dilution (multiple-dose fliptop vial) contains sodium chloride to render isotonic. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. pH is 3.6 (3.0 to 4.5). See table in ***HOW SUPPLIED*** for characteristics.

Sodium Chloride, USP, chemically designated NaCl, is a white crystalline compound freely soluble in water.

CLINICAL PHARMACOLOGY

Succinylcholine is a depolarizing skeletal muscle relaxant. As does acetylcholine, it combines with the cholinergic receptors of the motor end plate to produce depolarization. This depolarization may be observed as fasciculations. Subsequent neuromuscular transmission is inhibited so long as adequate concentration of succinylcholine remains at the receptor site. Onset of flaccid paralysis is rapid (less than one minute after intravenous administration), and with single administration lasts approximately 4 to 6 minutes.

Succinylcholine is rapidly hydrolyzed by plasma cholinesterase to succinylmonocholine (which possesses clinically insignificant depolarizing muscle relaxant properties) and then more slowly to succinic acid and choline (see ***PRECAUTIONS***). About 10% of the drug is excreted unchanged in the urine. Succinylcholine levels were reported to be below the detection limit of 2 µg/mL after 2.5 minutes of an IV bolus dose of 1 or 2 mg/kg in fourteen (14) anesthetized patients. The paralysis following administration of succinylcholine is progressive, with differing sensitivities of different muscles. This initially involves consecutively the levator muscles of the face, muscles of the glottis and finally the intercostals and the diaphragm and all other skeletal muscles.

Succinylcholine has no direct action on the uterus or other smooth muscle structures. Because it is highly ionized and has low fat solubility, it does not readily cross the placenta.

Tachyphylaxis occurs with repeated administration (see ***PRECAUTIONS***).

Depending on the dose and duration of succinylcholine administration, the characteristic depolarizing neuromuscular block (Phase I block) may change to a block with characteristics superficially resembling a non-depolarizing block (Phase II block). This may be associated with prolonged respiratory muscle paralysis or weakness in patients who manifest the transition to Phase II block. When this diagnosis is confirmed by peripheral nerve stimulation, it may sometimes be reversed with anticholinesterase drugs

such as neostigmine (see ***PRECAUTIONS***). Anticholinesterase drugs may not always be effective. If given before succinylcholine is metabolized by cholinesterase, anticholinesterase drugs may prolong rather than shorten paralysis.

Succinylcholine has no direct effect on the myocardium. Succinylcholine stimulates both autonomic ganglia and muscarinic receptors which may cause changes in cardiac rhythm, including cardiac arrest. Changes in rhythm, including cardiac arrest, may also result from vagal stimulation, which may occur during surgical procedures, or from hyperkalemia, particularly in pediatric patients (see ***PRECAUTIONS***: **Pediatric Use**). These effects are enhanced by halogenated anesthetics.

Succinylcholine causes an increase in intraocular pressure immediately after its injection and during the fasciculation phase, and slight increases which may persist after onset of complete paralysis (see ***WARNINGS***).

Succinylcholine may cause slight increases in intracranial pressure immediately after its injection and during the fasciculation phase (see ***PRECAUTIONS***).

As with other neuromuscular blocking agents, the potential for releasing histamine is present following succinylcholine administration. Signs and symptoms of histamine mediated release such as flushing, hypotension and bronchoconstriction are, however, uncommon in normal clinical usage.

Succinylcholine has no effect on consciousness, pain threshold or cerebration. It should be used only with adequate anesthesia (see ***WARNINGS***).

INDICATIONS AND USAGE

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.

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 (see ***WARNINGS***). 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. The precise time of onset and the duration of the risk period are not known.

WARNINGS

Succinylcholine should be used 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 carbon dioxide. The clinician must be prepared to assist or control respiration.

To avoid distress to the patient, succinylcholine should not be administered before unconsciousness has been induced. In emergency situations, however, it may be necessary to administer succinylcholine before unconsciousness is induced.

Succinylcholine is metabolized by plasma cholinesterase and should be used with caution, if at all, in patients known to be or suspected of being homozygous for the atypical plasma cholinesterase gene.

Anaphylaxis
Severe anaphylactic reactions to neuromuscular blocking agents, including succinylcholine, have been reported. These reactions have, in some cases, been life-threatening and fatal. Due to the potential severity of these reactions, the necessary precautions, such as the immediate availability of appropriate emergency treatment, should be taken. Precautions should also be taken in those individuals who have had previous anaphylactic reactions to other neuromuscular blocking agents since cross-reactivity between neuromuscular blocking agents, both depolarizing and non-depolarizing, has been reported in this class of drugs.

Risk of Death due to Medication Errors
Administration of QUELICIN results in paralysis, which may lead to respiratory arrest and death; this progression may be more likely to occur in a patient for whom it is not intended. Confirm proper selection of intended product and avoid confusion with other injectable solutions that are present in critical care and other clinical settings. If another healthcare provider is administering the product, ensure that the intended dose is clearly labeled and communicated.

Hyperkalemia
(see *BOX WARNING*) Succinylcholine should be administered with **GREAT CAUTION** to patients suffering from electrolyte abnormalities and those who may have massive digitalis toxicity, because in these circumstances succinylcholine may induce serious cardiac arrhythmias or cardiac arrest due to hyperkalemia.

GREAT CAUTION should be observed if succinylcholine is administered to patients during the acute phase of injury following major burns, multiple trauma, extensive denervation of skeletal muscle, or upper motor neuron injury (see ***CONTRAINDICATIONS***). 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. The precise time of onset and the duration of the risk period are undetermined. Patients with chronic abdominal infection, subarachnoid hemorrhage, or conditions causing degeneration of central and peripheral nervous systems should receive succinylcholine with **GREAT CAUTION** because of the potential for developing severe hyperkalemia.

Malignant Hyperthermia
Succinylcholine administration has been associated with acute onset of malignant hyperthermia, a potentially fatal hypermetabolic state of skeletal muscle. The risk of developing malignant hyperthermia following succinylcholine administration increases with the concomitant administration of volatile anesthetics. Malignant hyperthermia frequently presents as intractable spasm of the jaw muscles (masseter spasm) which may progress to generalized rigidity, increased oxygen demand, tachycardia, tachypnea and profound hyperpyrexia. Successful outcome depends on recognition of early signs, such as jaw muscle spasm, acidosis, or generalized rigidity to initial administration of succinylcholine for tracheal intubation, or failure of tachycardia to respond to deepening anesthesia. Skin mottling, rising temperature and coagulopathies may occur later in the course of the hypermetabolic process. Recognition of the syndrome is a signal for discontinuance of anesthesia, attention to increased oxygen consumption, correction of acidosis, support of circulation, assurance of adequate urinary output and institution of measures to control rising temperature. Intravenous dantrolene sodium is recommended as an adjunct to supportive measures in the management of this problem. Consult literature references and the dantrolene prescribing

information for additional information about the management of malignant hyperthermic crisis. Continuous monitoring of temperature and expired CO_2 is recommended as an aid to early recognition of malignant hyperthermia.

Other

In both adults and pediatric patients the incidence of bradycardia, which may progress to asystole, is higher following a second dose of succinylcholine. The incidence and severity of bradycardia is higher in pediatric patients than adults. 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. Pretreatment with anticholinergic agents (e.g., atropine) may reduce the occurrence of bradyarrhythmias.

Succinylcholine causes an increase in intraocular pressure. It should not be used in instances in which an increase in intraocular pressure is undesirable (e.g., narrow angle glaucoma, penetrating eye injury) unless the potential benefit of its use outweighs the potential risk.

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).

PRECAUTIONS: **(SEE BOX WARNING*)***

General

When succinylcholine is given over a prolonged period of time, 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 may be 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, depolarization of the type initially induced by succinylcholine (i.e., Phase I block) will be prolonged by an anticholinesterase agent.

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 ***DOSAGE 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, echothiophate, 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, 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 (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 QUELICIN 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***).

DOSAGE 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.

Risk of Medication Errors

Accidental administration of neuromuscular blocking agents may be fatal. Store QUELICIN 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 QUELICIN 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 arrythmias 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 QUELICIN to 1,000 or 500 mL sterile solution, such as 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP. Admixtures of QUELICIN must be used within 24 hours after preparation. Aseptic techniques should be used to prepare the diluted product. Admixtures of QUELICIN should be prepared for single patient use only. The unused portion of diluted QUELICIN should be discarded.

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

HOW SUPPLIED
QUELICIN™ (Succinylcholine Chloride Injection, USP) is supplied as a clear, colorless solution in the following concentrations and packages:

NDC No.	Container	Size (mL)	mg/mL	mg (total)	mOsmol/mL (calc.)
Single-dose					
0409-6970-10	Fliptop Vial	10 in 20	100	1000	0.830
Multiple-dose					
0409-6629-02	Fliptop Vial	10	20	200	0.338

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

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.

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-1246-1.3

Revised: 7/2018

ATTACHMENT 3

SUCCINYLCHOLINE CHLORIDE INJECTION, USP

A short-acting depolarizing skeletal muscle relaxant. Prefilled Syringe.

Rx Only

WARNING

RISK OF CARDIAC ARREST FROM HYPERKALEMIC RHABDOMYOLYSIS

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 were 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 should be 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 should be 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 (see ***PRECAUTIONS***: **Pediatric Use** and ***DOSAGE AND ADMINISTRATION***).

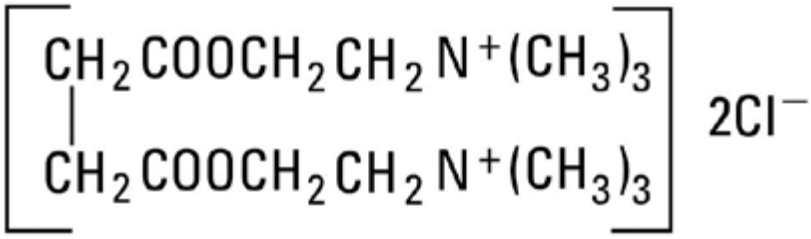
This drug should be used only by individuals familiar with its actions, characteristics and hazards.

DESCRIPTION

Succinylcholine Chloride Injection, USP is a sterile, nonpyrogenic solution to be used as an ultra short-acting, depolarizing, skeletal muscle relaxant See ***HOW SUPPLIED*** for summary of content and characteristics of the solutions. The solutions are for intramuscular (IM) or intravenous (IV) use.

Succinylcholine Chloride, USP is chemically designated $C_{14}H_{30}Cl_2N_2O_4$ and its molecular weight is 361.31.

It has the following structural formula:



Succinylcholine is a diquaternary base consisting of the dichloride salt of the dicholine ester of succinic acid. It is a white, odorless, slightly bitter powder, very soluble in water. The drug is incompatible with alkaline solutions but relatively stable in acid solutions. Solutions of the drug lose potency unless refrigerated.

Succinylcholine Chloride Injection, USP intended for single-dose administration contains no preservatives. Unused solution should be discarded. Sodium chloride added to render the solution isotonic. May contain sodium hydroxide and/or hydrochloric acid for pH adjustment. pH is 3.6 (3.0 to 4.5). See table in ***HOW SUPPLIED*** for characteristics.

Sodium Chloride, USP, chemically designated NaCl, is a white crystalline compound freely soluble in water.

CLINICAL PHARMACOLOGY

Succinylcholine is a depolarizing skeletal muscle relaxant. As does acetylcholine, it combines with the cholinergic receptors of the motor end plate to produce depolarization. This depolarization may be observed as fasciculations. Subsequent neuromuscular transmission is inhibited so long as adequate concentration of succinylcholine remains at the receptor site. Onset of flaccid paralysis is rapid (less than one minute after intravenous administration), and with single administration lasts approximately 4 to 6 minutes.

Succinylcholine is rapidly hydrolyzed by plasma cholinesterase to succinylmonocholine (which possesses clinically insignificant depolarizing muscle relaxant properties) and then more slowly to succinic acid and choline (see ***PRECAUTIONS***). About 10% of the drug is excreted unchanged in the urine. Succinylcholine levels were reported to be below the detection limit of 2 μg/mL after 2.5 minutes of an IV bolus dose of 1 or 2 mg/kg in fourteen (14) anesthetized patients. The paralysis following administration of succinylcholine is progressive, with differing sensitivities of different muscles. This initially involves consecutively the levator muscles of the face, muscles of the glottis and finally the intercostals and the diaphragm and all other skeletal muscles.

Succinylcholine has no direct action on the uterus or other smooth muscle structures. Because it is highly ionized and has low fat solubility, it does not readily cross the placenta. Tachyphylaxis occurs with repeated administration (see ***PRECAUTIONS***).

Depending on the dose and duration of succinylcholine administration, the characteristic depolarizing neuromuscular block (Phase I block) may change to a block with characteristics superficially resembling a non-depolarizing block (Phase II block). This may be associated with prolonged respiratory muscle paralysis or weakness in patients who manifest the transition to Phase II block. When this diagnosis is confirmed by peripheral nerve stimulation, it may sometimes be reversed with anticholinesterase drugs such as neostigmine (see ***PRECAUTIONS***). Anticholinesterase drugs may not always be effective. If given before succinylcholine is metabolized by cholinesterase, anticholinesterase drugs may prolong rather than shorten paralysis.

Succinylcholine has no direct effect on the myocardium. Succinylcholine stimulates both autonomic ganglia and muscarinic receptors which may cause changes in cardiac rhythm, including cardiac arrest. Changes in rhythm,

including cardiac arrest, may also result from vagal stimulation, which may occur during surgical procedures, or from hyperkalemia, particularly in pediatric patients (see ***PRECAUTIONS***: **Pediatric Use**). These effects are enhanced by halogenated anesthetics.

Succinylcholine causes an increase in intraocular pressure immediately after its injection and during the fasciculation phase, and slight increases which may persist after onset of complete paralysis (see ***WARNINGS***).

Succinylcholine may cause slight increases in intracranial pressure immediately after its injection and during the fasciculation phase (see ***PRECAUTIONS***).

As with other neuromuscular blocking agents, the potential for releasing histamine is present following succinylcholine administration. Signs and symptoms of histamine mediated release such as flushing, hypotension and bronchoconstriction are, however, uncommon in normal clinical usage.

Succinylcholine has no effect on consciousness, pain threshold or cerebration. It should be used only with adequate anesthesia (see ***WARNINGS***).

INDICATIONS AND USAGE

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.

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 (see ***WARNINGS***). 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. The precise time of onset and the duration of the risk period are not known.

WARNINGS

Succinylcholine should be used 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 carbon dioxide. The clinician must be prepared to assist or control respiration.

To avoid distress to the patient, succinylcholine should not be administered before unconsciousness has been induced. In emergency situations, however, it may be necessary to administer succinylcholine before unconsciousness is induced.

Succinylcholine is metabolized by plasma cholinesterase and should be used with caution, if at all, in patients known to be or suspected of being homozygous for the atypical plasma cholinesterase gene.

Anaphylaxis

Severe anaphylactic reactions to neuromuscular blocking agents, including succinylcholine, have been reported. These reactions have, in some cases, been life-threatening and fatal. Due to the potential severity of these reactions, the necessary precautions, such as the immediate availability of appropriate emergency treatment,

should be taken. Precautions should also be taken in those individuals who have had previous anaphylactic reactions to other neuromuscular blocking agents since cross-reactivity between neuromuscular blocking agents, both depolarizing and non-depolarizing, has been reported in this class of drugs.

Risk of Death due to Medication Errors

Administration of succinylcholine chloride results in paralysis, which may lead to respiratory arrest and death; this progression may be more likely to occur in a patient for whom it is not intended. Confirm proper selection of intended product and avoid confusion with other injectable solutions that are present in critical care and other clinical settings. If another healthcare provider is administering the product, ensure that the intended dose is clearly labeled and communicated.

Hyperkalemia

(see *BOX WARNING*) Succinylcholine should be administered with **GREAT CAUTION** to patients suffering from electrolyte abnormalities and those who may have massive digitalis toxicity, because in these circumstances succinylcholine may induce serious cardiac arrhythmias or cardiac arrest due to hyperkalemia.

GREAT CAUTION should be observed if succinylcholine is administered to patients during the acute phase of injury following major burns, multiple trauma, extensive denervation of skeletal muscle, or upper motor neuron injury (see ***CONTRAINDICATIONS***). 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. The precise time of onset and the duration of the risk period are undetermined. Patients with chronic abdominal infection, subarachnoid hemorrhage, or conditions causing degeneration of central and peripheral nervous systems should receive succinylcholine with **GREAT CAUTION** because of the potential for developing severe hyperkalemia.

Malignant Hyperthermia

Succinylcholine administration has been associated with acute onset of malignant hyperthermia, a potentially fatal hypermetabolic state of skeletal muscle. The risk of developing malignant hyperthermia following succinylcholine administration increases with the concomitant administration of volatile anesthetics. Malignant hyperthermia frequently presents as intractable spasm of the jaw muscles (masseter spasm) which may progress to generalized rigidity, increased oxygen demand, tachycardia, tachypnea and profound hyperpyrexia. Successful outcome depends on recognition of early signs, such as jaw muscle spasm, acidosis, or generalized rigidity to initial administration of succinylcholine for tracheal intubation, or failure of tachycardia to respond to deepening anesthesia. Skin mottling, rising temperature and coagulopathies may occur later in the course of the hypermetabolic process. Recognition of the syndrome is a signal for discontinuance of anesthesia, attention to increased oxygen consumption, correction of acidosis, support of circulation, assurance of adequate urinary output and institution of measures to control rising temperature. Intravenous dantrolene sodium is recommended as an adjunct to supportive measures in the management of this problem. Consult literature references and the dantrolene prescribing information for additional information about the management of malignant hyperthermic crisis. Continuous monitoring of temperature and expired CO_2 is recommended as an aid to early recognition of malignant hyperthermia.

Other

In both adults and pediatric patients the incidence of bradycardia, which may progress to asystole, is higher following a second dose of succinylcholine. The incidence and severity of bradycardia is higher in pediatric patients than adults. 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. Pretreatment with anticholinergic agents (e.g., atropine) may reduce the occurrence of bradyarrhythmias.

Succinylcholine causes an increase in intraocular pressure. It should not be used in instances in which an increase in intraocular pressure is undesirable (e.g., narrow angle glaucoma, penetrating eye injury) unless the potential benefit of its use outweighs the potential risk.

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).

PRECAUTIONS: (SEE BOX WARNING)

General

When succinylcholine is given over a prolonged period of time, 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 may be 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, depolarization of the type initially induced by succinylcholine (i.e., Phase I block) will be prolonged by an anticholinesterase agent.

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 ***DOSAGE 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, echothiophate, 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, 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 (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 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***).

To report SUSPECTED ADVERSE REACTIONS, contact XXXXXX Pharmaceuticals at X-XXX-XXX-XXXX or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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***).

DOSAGE 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.

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 arrythmias 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 as a single-dose in the following concentrations and packages:

NDC No.	**Container**	**Size (mL)**	**mg/mL**	**mg (total)**	**mOsmol/mL (calc.)**
NDC XXXXX-XXXX-X	Single-dose Prefilled Syringe	5	20	100	0.830
NDC XXXXX-XXXX-X	Single-dose Prefilled Syringe	10	20	200	0.830

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

Store in refrigerator 2° to 8°C (36° to 46°F).
Manufactured by: TBD

Rev. 10-2020-00

ATTACHMENT 4

EXAMPLES OF 5ML AND 10ML SINGLE USE PREFILLED SYRINGES FOR SUCCINYLCHOLINE CHLORIDE INJECTION 20MG/ML, AVAILABLE THROUGH DRUG COMPOUNDING OUTSOURCING FACILITIES REGISTERED UNDER SECTION 503B OF THE FD&C ACT:

ENTITY	AVAILABILITY	SOURCE
EDGE PHARMA	Succinylcholine Unit Dose Syringe - 20 mg/mL in 5 mL	https://edgepharma.com/products/anesthesiology/succinylcholine/
NEPHRON PHARM	Succinylcholine Chloride Injection USP 200 mg/10 mL (20 mg/mL) Preservative Free- Single Dose pre-filled 10mL syringes	https://www.nephronpharm.com/products/succinylcholine-chloride-injection-usp-200-mg10-ml-20-mgml-preservative-free
SCA PHARMA	Succinylcholine 20 mg/mL 5 mL fill 6 mL syringe Succinylcholine 20 mg/mL 10 mL fill 12 mL syringe	SCA PRODUCT LIST 2019/PDF
LEITERS	Succinylcholine 20 mg/mL -5 mL syringe Succinylcholine 20 mg/mL -10 mL syringe	https://leiters.com/wp-content/uploads/2020/05/Leiters-Catalog-LEI-MKT6-05_2020.pdf
STERRX	Succinylcholine Chloride Injection (20mg/mL)- 10 mL syringe	https://www.sterrx.com/Injectables
CAPS	Succinylcholine 20 mg/mL 5 mL in 5 mL BD Syringe Succinylcholine 20 mg/mL 10 mL in 10 mL BD Syringe	https://www.capspharmacy.com/content/dam/caps/us/website/product-catalog/CAPS_Catalog_June_2017_FINAL.pdf