**Succinolin® (Suxamethonium) Injection – Product Information**

**Composition**

*Active ingredient:* Suxamethonii chloridum anhydricum.

*Excipients:* water for injection.

In addition vial: Conserv. E 217 and E 219th

**Dosage form and amount of active ingredient per unit**

*Solution for injection 5%*

1 ampoule breaker 2 ml contains 100 mg Suxamethonii chloridum anhydricum.

1 vial of 10 ml contains 500 mg Suxamethonii chloridum anhydricum.

**Indications / Applications**

Short-term muscle relaxation for intubation prior to surgery, and obstetrics. To Dauerrelaxation for short procedures requiring a well-controlled relaxation. Furthermore, to facilitate the reduction of fractures and dislocations, for Mitigation of convulsions in electric shock treatment.

**Dosage / Application**

The dosage is based on body weight. Doses of about 0.1 mg / kg body weight have a muscle spasticity generally without significant influence on the respiratory activity result. Doses of 0.2 to 1.0 mg / kg lead to the complete relaxation of the abdominal wall and skeletal muscle as well as extensive restriction or complete cessation of spontaneous breathing.

*Usual dosage*

Reduction of fractures, etc.: 0.1-0.2 mg / kg iv

Electric shock: 0.1-1.0 mg (partial or Vollmitigierung).

Kurzrelaxation such as intubation: 0.5-1.0 mg / kg iv If iv administration is not possible, in the 1-2 mg / kg, a maximum of 150 mg.

Dauerrelaxation: 2-4 mg / min IV infusion relax the abdominal muscles and skeleton, 4-8 mg / min and the diaphragm.

Administration in 0.1-0.2% concentration with isotonic saline or dextrose solution.

Fractionated administration: Introduction to 20-80 mg iv repeated injections of 3-5 mg iv as required.

*Special dosage instructions*

A prolonged effect is common in: ileus, heart failure, malignancy, especially bronchus-CA, anemia, chronic inflammation, cachexia, dehydration under the action of cytotoxic drugs and ophthalmic cholinesterase inhibitors among others.

For instructions, see "Interactions".
These doses should be adjusted accordingly.

*Children*

Toddlers (28 days - 23 months) and neonatal (4-27 days) (see also "Special warnings and precautions for use"): 2 mg / kg body weight iv as a bolus.

Children (2-11 years) (see also "Special warnings and precautions for use"): Recommended Dose: 1 mg / kg body weight.

Younger children do not speak so well on the neuromuscular blockade.

*in the application*

Maximum dose: 150 mg.

Toddlers (28 days - 23 months) and neonatal (4-27 days) 4-5 mg / kg body weight.

Children (2-11 years) to 4 mg / kg body weight.

Muscle relaxation is reached after about 3 minutes.

*Special populations*

*Dosage in hepatic insufficiency*

The dose of suxamethonium should be reduced in patients with severe liver disease or cirrhosis, since the activity of plasma cholinesterase pseudo is reduced.

*Dosage in renal insufficiency*

Patients with renal impairment or hemodialysis require a dose adjustment of suxamethonium, while the serum potassium is normal. In serum potassium above 5.5 mmol / l after administration of suxamethonium the risk of fatal cardiac complications is increased.

*Dosage in geriatric patients*

The required dose of suxamethonium in geriatric patients is comparable with that in adults.

*Contraindications*

Succinolin is contraindicated in:

- Hypersensitivity to the active substance, to any of the excipients or succinylcholine;
- Patients with preserved consciousness that can not be ventilated due to morphological and functional defects;
- Patients in whom malignant hyperthermia or disposition to be made of the history (personal or family history) known in unexpected hyperthermia Succinolin should be discontinued immediately and as quickly as possible to inject dantrolene sodium;
- Patients with severe hepatic impairment.

Succinolin may lead to increases in serum potassium levels and cause under adverse conditions, severe arrhythmia and cardiac arrest.

For these reasons Succinolin is also contraindicated in:
In patients who are in the healing phase of a severe trauma. The risk of a sharp increase in potassium release by succinylcholine occurs in these patients is not immediately, but begins 5-15 days after injury. It can last for 2-3 months while sepsis.

In patients with severe burns, as between the 10th and 66th day after the event is also an increased potassium release occur.

In patients with neurological disorders who have an acute muscle atrophy result, there may also be increased potassium secretion within the first 6 months based on the strength and extent of muscle paralysis. The same is also true for patients who are immobilized for a long period.

In patients who had a history of hyperkalemia.

Succinolin should not be administered to patients with congenital myotonic diseases such as myotonia congenita and dystrophia myotonica, since it can occasionally be severe myotonic spasms.

Succinolin should also be avoided in patients with Duchenne muscular dystrophy because an application may be associated with rigidity, hyperthermia, hyperkalemia, myoglobinaemia, cardiac arrest and postoperative respiratory depression.

Succinolin slightly increased temporarily intraocular pressure and therefore should not be used in open injuries of the eye or the eyeball, or when an increase in intraocular pressure should be avoided, and glaucoma.

**Warnings and Precautions**

Succinolin may be used only when enough experience in handling liabilities and when the requirement for intubation and mechanical ventilation are given.

Caution should be exercised in patients with known hypersensitivity to other neuromuscular blocking agents, even with administration of Succinolin, because of reports of cross-sensitivity between neuromuscular blocking agents are present.

After application of Suxamethoniumchlorid cases of uncorrectable cardiac arrest in children and adolescents have become known. These were in some hitherto unrecognized neuromuscular diseases before. Because of the severity of the side effects is recommended to limit the application of Suxamethoniumchlorid even in apparently healthy children and adolescents in situations where an immediate intubation or maintenance of a patent airway in emergency situations is required.

Particular caution should be exercised when: heart disease, uremia (particularly at high serum levels), pheochromocytoma, paroxysmal idiopathic myoglobinuria, respiratory failure, exposure to phosphoric acid esters.

Prolonged relaxation, possibly with apnea can be caused by "atypical" Serumcholinesterase, a hereditary deficiency of Serumcholinesterase or a temporary reduction in the Serumcholinesterase: such as in severe liver disease, severe anemia, with starvation, in cachexia, dehydration, fevers, after acute poisoning or chronic intake of cholinesterase-inhibitor-containing insecticides or drugs (phospholine, demecarium, neostigmine, phystostigmine, distigmine) and with the concomitant use of drugs that compete with succinylcholine to the enzyme (procaine iv).

**Interactions**

The specification of Succinolin enhances the effect of non-depolarizing relaxants. The default non-depolarizing relaxants alleviate or prevent side effects of Succinolin.
The cardiovascular side effects are amplified by halogenated anesthetics (halothane), attenuated by thiopental and atropine.

The neuromuscular blocking effect of Succinolin is amplified by aminoglycosides, polypeptide antibiotics and tetracycline, amphotericin B, cyclopane, Propranidid, quinidine, thiopeta, parasympathomimetics incl. Cholinestherasemhemmer, procaine, lidocaine, ajmaline, beta blockers, calcium channel blockers, cyclophosphamide, Thiophosphamid, oxytocin, cimetidine, metoclopramide, perphenazine, phenothiazine, lithium, oral contraceptives.

The concomitant administration of anesthetic agents should be avoided, also the Succinolin-induced muscle damage amplified as it increases the risk of developing malignant hyperthermia and.

The effect of digitalis is Suxamethoniumchlorid amplified (risk of the occurrence of arrhythmias).

Co-administration of strong analgesics can cause respiratory depression and atelectasis.

Simultaneous infusion of blood or plasma reduces the Succinolin effect.

Under the influence of alcohol and other CNS depressants, the symptoms of overdose occur strengthened.

**Pregnancy / Lactation**

There are no controlled studies in animals or pregnant women available. After high doses in the mother (from 2-3 mg / kg) a relaxation of the fetus or newborn is possible despite low diaplazentar passage.

Succinolin must not be administered unless clearly necessary during pregnancy.

During the application of Succinolin shall not be quenched.

**Effect on the ability to drive and use machines**

Following administration of Succinolin under general anesthesia, the patient may not actively participate in the road or operate machinery for 24 hours. This warning refers more to the same anesthetic used as the muscle relaxant.

**Adverse effects**

Suxamethonium has several potentially dangerous unwanted effects.

The most common adverse effects include: muscle pain (60%) and muscular fasciculations (90%), and non-lethal acute increase in serum potassium (100%). Very often slight bradycardia (50% of children less often in adults) and myoglobinemia (20% of children). There is often elevated intraocular pressure and intragastric and hypersensitivity reactions such as paroxysmal erythema (reddening).

The most dangerous are the following adverse effects that occur rarely, but are always to prefer the administration of suxamethonium are:

Increases in serum potassium with arrhythmia and cardiac arrest, malignant hyperthermia, anaphylactic shock, rhabdomyolysis and myoglobinuria with renal failure and prolonged paralysis.

Muscle pain occurs frequently, preferably in ambulatory patients under general anesthesia for short procedures. A direct correlation between the degree of muscular fasciculation and the incidence or severity of the pain seem not given. The administration of a small dose of a nondepolarizing muscle
relaxant suxamethonium few minutes before the administration appears to reduce the incidence and intensity of muscle pain.

To create good conditions for endotracheal intubation, higher doses of suxamethonium than 1 mg/kg should be administered with this technique.

Succinylcholine causes a Depolarisationsblock with initial contractions, which are often seen as muscular fasciculation. In rare cases, the Depolarisationsblock in a long-lasting curareformen block pass, when fractionated Succinolin is for an extended period with a total dose of about 3-5 mg/kg body weight (dual block).

**Immune system**

*Common*: hypersensitivity reactions (attacks of erythema, urticaria).

*Rare*: bronchospasm.

*Very rare*: anaphylactic shock.

**Metabolism and Nutrition**

*Very common*: hyperkalemia (100%).

*Very rare* life-threatening hyperkalemia. Porphyria.

**Eyes**

*Common*: Elevated intraocular pressure (possibly due to contraction of the external eye muscles and increased congestion of the choroid).

**Heart**

*Very common*: arrhythmias (slight bradycardia, nodal rhythm, extrasystoles) occur after the first intravenous injection in 50% of children and 20% of adults. In infants and young children, the incidence is greatest. Regardless of the age increases the incidence of cardiac arrhythmias, if within 15 minutes after the first dose, a second dose is given. The incidence of bradycardia can be reduced by prior administration of atropine.

*Uncommon*: transient increases in blood pressure, tachycardia.

*Very rare*: ventricular arrhythmia, ventricular fibrillation due to hyperkalemia. Cardiac arrest due to succinylcholine-induced hyperkalemia, especially in children with undiagnosed skeletal myopathy (Duchenne muscular dystrophy).

**Muscle, skeletal system**

Myoglobinæmia (at 20% of the children after intravenous administration of suxamethonium in adults less common). The myoglobinæmia is not dose dependent and can occur with or without fasciculations.

**Renal and urinary**

*Rare*: myoglobinuria, and increased CPK (creatine phosphokinase), mainly in children after administration of succinylcholine and halothane.

*Very rare*: myoglobinuria with renal failure (mainly in patients with (latent) muscular dystrophy).
**Common Problems**

*Very rare:* malignant hyperthermia (0.002% of adults and 0.006% of the children, or one of 15'000-150'000 anesthesia) with or without increased muscle tone (hard to influencing spasm of the muscles of mastication), cardiovascular complications (hyperventilation, labile blood pressure) and temperature rise, severe acidosis, hyperkalemia, hemoglobinuria and myoglobinuria.

**Reduced effect**

A shortened effect may arise due to increased enzyme activity, which leads to an accelerated degradation, wherein itself can arise against high doses resistance. Are rare (1: 1400) in diabetes mellitus, hyperthyroidism, hypertension.

**Overdose**

Overdose causes prolonged apnea, which must be treated with artificial respiration.

In case of poisoning with suxamethonium a short-acting Cholinesterasehemmstoff (10 mg edrophonium chloride) can be tried. When an obvious improvement can be maintained for a few minutes, then the application of 1-2 mg neostigmine is also possible. The immediate use of neostigmine is to avoid it.

**Features / Effects**

ATC code: M03AB01

**Mechanism of action**

Suxamethonium is a choline derivative (succinylcholine chloride or Succinylbischolin) having substantially lower muscarinic effects as acetylcholine. How this it causes a depolarization of the muscle cell membrane (initial muscular fasciculation). It is not inactivated by the acetylcholinesterase the tissue, but rather by the Serumcholinesterase. Therefore, the depolarization and thus the excitability of nerve impulses against persists until suxamethonium diffuses due to drop its serum concentration of the tissue.

By iv continuous infusion or repeated injection (fractional administration) can be achieved Dauererrelaxation whose strength can be adapted to the requirements of the operation quickly.

**Pharmacokinetics**

**Absorption**

Suxamethoniumchlorid is absorbed as other quaternary ammonium compounds very poorly and to varying extent from the gastrointestinal tract.

After intravenous administration first effects are observed after just 30 seconds. The duration of action is about 2 minutes; After about 8-10 minutes is expected to complete offset of effect. Due to this rapid onset and short duration of action is different from suxamethonium muscle relaxants Curaretyps.
Suxamethonium has in comparison to other peripheral muscle relaxants the most rapid onset of action.

Distribution
The protein binding is 30%: the placental permeability is low; the blood-brain barrier is not happening.

Metabolism
Succinolin, a Bischolinester of succinic acid, acts according to usual doses only about 10 minutes because the substance is rapidly degraded by nonspecific cholinesterases to Succinylmonocholin - the effect is 10 times weaker relaxing effect - and is further hydrolyzed to choline and succinic acid.

Elimination
Only a small proportion (about 10%) of the administered Suxamethoniums is excreted unchanged. The elimination half-life is 1-2 minutes; t½ is prolonged by liver insufficiency, but not by renal impairment.

Preclinical data
There are no studies on the mutagenic, carcinogenic and embryotoxic potential.

Other information
Incompatibilities
Succinolin must not be such as barbiturates, mixed with alkaline substances (precipitation).

Durability
The preparation may be used only to the one indicated on the container after "EXP" date.

Special precautions for storage
Succinolin ampoules should be stored in the refrigerator (2-8 ° C) and protected from light.

Instructions for use
Succinolin must, like all muscle relaxants peripherally acting, be applied by physicians anesthesiological training and experience in endotracheal intubation and mechanical ventilation. The necessary equipment must be available.

Succinolin ampoules are compatible with blood isotonic sodium chloride, Ringer, 5% fructose, dextrose 5% and 6% dextran solution. It should be used only freshly prepared solutions; Unopened vials solutions not used and should be discarded.