MIVACRON
MIVACURIUM CHLORIDE

CHOOSE MIVACRON® FOR SHORT-DURATION BLOCKADE, REVERSAL OPTIONAL*

INDICATION[1]

MIVACRON® (mivacurium chloride) injection is a short-acting neuromuscular blocking agent indicated for inpatients and outpatients, as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

SAFETY CONSIDERATIONS[1]

MIVACRON is contraindicated in patients with known hypersensitivity to the product and its components.
Severe anaphylactic reactions to neuromuscular blocking agents, including MIVACRON, have been reported.
MIVACRON should only be administered intravenously in carefully adjusted dosage by or under the supervision of experienced clinicians who are familiar with the drug's actions and the possible complications. MIVACRON is metabolized by plasma cholinesterase and should be used with great caution, if at all, in patients suspected of being homozygous for the atypical plasma cholinesterase gene. MIVACRON will not counteract bradycardia and requires individualized dosing for conditions causing potentiation of or resistance to neuromuscular block or conditions suggesting a greater sensitivity to histamine release. Certain drugs may potentiate the neuromuscular blocking action of the drug.

*MIVACRON is reversible, but in clinical trials, a majority of patients achieved complete recovery of muscle function without a reversal agent. 95% spontaneous muscle recovery (twitch recovery response) may be expected in 25-35 minutes, depending on dose[1]

Please see Important Safety Information on pages 2-3
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Mivacron® injection
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**SHORT BLOCK.
REVERSAL OPTIONAL.**

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INDICATION AND IMPORTANT SAFETY INFORMATION[1]

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INDICATION[1]

MIVACRON® (mivacurium chloride) injection is a short-acting neuromuscular blocking agent indicated for inpatients and outpatients, as an adjunct to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

IMPORTANT SAFETY INFORMATION[1]

- MIVACRON is contraindicated in patients with known hypersensitivity to the product and its components.
- Severe anaphylactic reactions to neuromuscular blocking agents, including MIVACRON, have been reported. These reactions have in some cases been life-threatening and fatal. Necessary precautions, including the immediate availability of appropriate emergency treatment, should be taken. Precautions should also be taken in individuals who have had previous anaphylactic reactions to other neuromuscular blocking agents.
- **MIVACRON should only be administered intravenously in carefully adjusted dosage by or under the supervision of experienced clinicians who are familiar with the drug's actions and the possible complications.**
- **It is recommended that a peripheral nerve stimulator be used during the administration of MIVACRON to monitor drug effect, determine the need for additional drug, and confirm recovery from neuromuscular block.**
- **MIVACRON has no known effect on consciousness, pain threshold, or cerebration.**
- **MIVACRON is metabolized by plasma cholinesterase and should be used with great caution, if at all, in patients suspected of being homozygous for the atypical plasma cholinesterase gene due to the possibility of prolonged neuromuscular block.** Plasma cholinesterase activity may be diminished in patients with genetic abnormalities of plasma cholinesterase, pregnancy, liver or kidney disease, malignant tumors, infections, burns, anemia, decompensated heart disease, peptic ulcer, or myxedema. The neuromuscular blocking effect of MIVACRON 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.
- Exercise caution when administering MIVACRON to patients with clinically significant cardiovascular disease, obesity, or any history suggesting sensitivity to the release of histamine (e.g., asthma), as a transient decrease in mean arterial pressure related to histamine release is possible.
- MIVACRON will not counteract the bradycardia produced by many anesthetic agents or by vagal stimulation.
- Doses of MIVACRON should be individualized for drugs or conditions causing potentiation of or resistance to neuromuscular block. The following may cause potentiation: neuromuscular diseases, burns, acid-base and/or serum electrolyte abnormalities, cachexia, debilitation, and carcinomatosis. The following may cause resistance: burns, acid-base and/or serum electrolyte abnormalities, and chronic administration of phenytoin or carbamazepine.
- Isoflurane or enflurane administered with nitrous oxide/oxygen to achieve 1.25 MAC decreases the ED_{50} of MIVACRON. Other drugs which may enhance the neuromuscular blocking action of nondepolarizing agents such as MIVACRON include certain antibiotics (e.g., aminoglycosides, tetracyclines, bacitracin, polymyxins, lincomycin, clindamycin, colistin, and sodium colistimethate), magnesium salts, lithium, local anesthetics, procainamide, quinidine, and succinylcholine.
- Adverse events: >1% of the surgical patients treated with MIVACRON during clinical trials reported flushing (16%); <1% of patients reported hypotension, tachycardia, bradycardia, cardiac arrhythmia, phlebitis, bronchospasm, wheezing, hypoxemia, rash, urticaria, erythema, injection site reaction, prolonged drug effect, dizziness, or muscle spasms.

References:

1. MIVACRON [package insert]. North Chicago, IL: AbbVie Inc.
2. Apfelbaum JL. Mivacurium chloride administration by infusion. *Acta Anaesthesol Scand.* 1995;39(suppl s106):55-57.
3. Data on file, Abbvie Inc.
4. Savarese JJ, Ali HH, Basta SJ, et al. The clinical neuromuscular pharmacology of mivacurium chloride (BW B1090U). A short-acting nondepolarizing ester neuromuscular blocking drug. *Anesthesiology.* 1988;68(5):723-732.
5. Tang J, Joshi GP, White PF. Comparison of rocuronium and mivacurium to succinylcholine during outpatient laparoscopic surgery. *Anesth Analg.* 1996;82:994-998.

FLEXIBILITY

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MIVACRON® (mivacurium chloride) INJECTION IS EASY TO TITRATE TO INDIVIDUAL PATIENT REQUIREMENTS[1,2]

MIVACRON provides the flexibility of multiple bolus dosing options[1]

Recommended initial dosing regimen[1]

Children 2 to 12 years:

over
5–15 seconds

Delivers **~10 minutes** of clinically effective neuromuscular block[a]

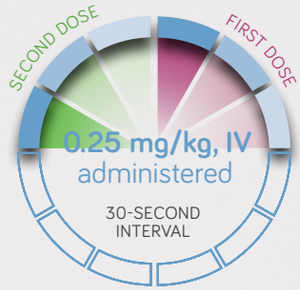
Adults:

over
5–15 seconds

Delivers **~16 minutes** of clinically effective neuromuscular block[a]

over
30 seconds

Delivers **~20 minutes** of clinically effective neuromuscular block[a]



in divided doses
(0.15 mg/kg
followed in 30 seconds by
0.1 mg/kg)

Delivers **~23 minutes** of clinically effective neuromuscular block[a]

DOSING CONSIDERATIONS:
In patients with clinically significant cardiovascular disease and in patients with any history suggesting a greater sensitivity to the release of histamine or other mediators, the initial dose of MIVACRON should be 0.15 mg/kg or less, administered over 60 seconds.

Maintenance dosing for additional neuromuscular blockade[1]

over
5–15 seconds

Delivers **~15 minutes**[b] of clinically effective neuromuscular block[c]

[a]Range in clinical trials: 9–38 minutes at 0.15 mg/kg, 10–36 minutes at 0.2 mg/kg, 14–38 minutes at 0.25 mg/kg
[b]Time to 25% spontaneous recovery
[c]For shorter or longer durations of action, smaller or larger maintenance doses may be administered

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SAFETY CONSIDERATIONS[1]

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- **It is recommended that a peripheral nerve stimulator be used during the administration of MIVACRON to monitor drug effect, determine the need for additional drug, and confirm recovery from neuromuscular block.**
- **Administration of MIVACRON in doses ≤0.15 mg/kg over 5 to 15 seconds is associated with minimal changes in mean arterial blood pressure (MAP) or heart rate (HR). Higher doses ≥0.2 mg/kg may be associated with transient decreases in MAP and increases in HR in some patients.**

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INTUBATION

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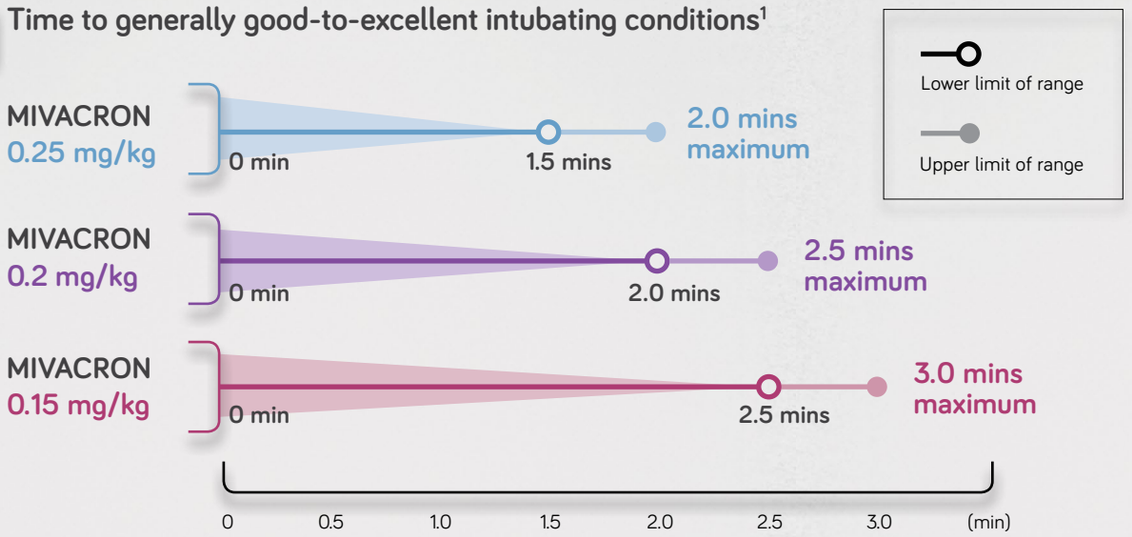
MIVACRON PROVIDES GOOD-TO-EXCELLENT INTUBATING CONDITIONS WITHIN 1.5–3 MINUTES, DEPENDING ON THE DOSE[1*†]

Time to generally good-to-excellent intubating conditions[1]



When administered during the induction of adequate general anesthesia using thiopental or propofol, nitrous oxide/oxygen, and coinduction agents such as fentanyl and/or midazolam, doses of 0.15 mg/kg (2 x ED_{95}) MIVACRON administered over 5–15 seconds or 0.2 mg/kg MIVACRON administered over 30 seconds produced generally good-to-excellent tracheal intubation conditions in 2.5–3 and 2–2.5 minutes, respectively. A dose of 0.25 mg/kg MIVACRON administered as a divided dose (0.15 mg/kg followed 30 seconds later by 0.1 mg/kg) produced generally good-to-excellent intubation conditions in 1.5–2 minutes after initiating the dosing regimen.[1]

*Dosing range studied: 0.15 mg/kg (2.5-3 mins) to 0.25 mg/kg (1.5-2 mins)

†After completion of 0.15 mg/kg to 0.25 mg/kg dose

Timing of intubation

For optimal intubating results

- Visually examine the vocal cords 90 seconds after the first dose of MIVACRON
- The cords should be relaxed, indicating that conditions are right for successful intubation

Use multiple criteria to guide the time of intubation

- Reliance upon twitch monitoring of the adductor pollicis may result in waiting too long and therefore missing the time frame for optimal intubating conditions
- All four twitches of the train-of-four response may be present, with little or no fade, at the times recommended for intubation[1]

As with other neuromuscular blocking agents, it is important to use other criteria, such as clinical evaluation of the status of relaxation of jaw muscles and vocal cords, in conjunction with peripheral muscle twitch monitoring, to guide the appropriate time of intubation[1]

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MIVACRON: Ready to use

Available in ready-to-use 5- and 10-mL single-dose vials

- 2 mg mivacurium in each mL
- No refrigeration
- No reconstitution required

Single-Dose Fliptop Vial
NDC: 0074-4365-10

10 per carton

10 mL

Single-Dose Fliptop Vial
NDC: 0074-4365-05

10 per carton

5 mL

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CHOOSE MIVACRON: THE ONLY SHORT-ACTING, NONDEPOLARIZING NMB[3]

- **A short-acting, nondepolarizing neuromuscular blocking agent available for short surgical procedures requiring general anesthesia.[1] In adults, you may expect MIVACRON 0.15 mg/kg to deliver 15–20 minutes of blockade[1*]**
- **MIVACRON is reversible, but in clinical trials, a majority of patients achieved complete recovery of muscle function without a reversal agent[1]**
- **Fast offset (average time 12–13 minutes across all doses) from neuromuscular blockade[1†]**
- **95% spontaneous muscle recovery may be expected in 25–35 minutes, depending on the dose[1‡]**
  - MIVACRON is not associated with cumulative neuromuscular blocking effects during repeated maintenance doses[1]
  - In clinical trials, spontaneous recovery from induced blockade was rapid, and acetylcholinesterase inhibitors were infrequently administered to antagonize residual paralysis[4,5]
- **Good-to-excellent intubating conditions within 1.5–3 minutes, depending on the dose[1§]**
  - Dosing range studied: 0.15 mg/kg (2.5–3 mins) to 0.25 mg/kg (1.5–2 mins)
- **Easy titration to individual patient requirements[1,2]**
- **Rapid administration of MIVACRON will increase the risk of flushing[1]**
  - Histamine release is related to speed of administration and dose[1]
  - Fewer than 2% of flushing episodes after treatment with 0.15 mg/kg dosing resulted in hypotension, which required no treatment[1]
  - Fewer than 1% of these episodes resulted in moderate wheezing, which was successfully treated[1]

SAFETY CONSIDERATIONS[1]

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*Range in clinical trials at 0.15 mg/kg dosing: 9–38 minutes

†Offset for all doses was the time interval between 25% recovery to T_4/T_1 ratio recovery to ≥75%

‡Spontaneous recovery for 0.15 mg/kg and 0.20 mg/kg doses defined as 95% recovery of the muscle twitch response or T_4/T_1 ratio recovery to ≥75%

§After completion of 0.15 mg/kg to 0.25 mg/kg dose

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120-1930449 December 2017

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