PRESCRIBING INFORMATION

ACURON® Injection IV

ایکیورون
انجکشن آئی وی

(Atracurium Besylate Injection USP)

Composition:
Each ml contains
Atracurium Besylate USP.....10.0 mg
Mfg. Specs. Brookes

Description:
Acuron (Atracurium Besylate) is an intermediate acting competitive non-depolarizing, skeletal muscle relaxant for intravenous administration. Acuron (Atracurium Besylate) is a sterile, nonpyrogenic aqueous solution. Each ml contains 10 mg Atracurium Besylate. The pH is adjusted to 3.25 to 3.65 with benzenesulfonic acid.

Clinical Pharmacoloy:
Acuron(Atracurium Besylate) is a non-depolarizing agents that antagonize the neurotransmiter action of acetylcholine by binding competitively with cholinergic receptor sites on the motor end-plate. The duration of neuromuscular blockade produced by Acuron is approximately one-third to one half the duration of blockade of d-tubocurarine and pancuronium at initially equipotent doses.

As with other non-depolarizing neuromuscular blockade, the time to onset of paralysis decreases and duration of maximum effect increases with increasing Acuron doses.

Repeated administration of maintenance doses of Acuron has no cumulative effect on the duration of neuromuscular blockade if recovery is allowed to begin prior to repeat dosing, moreover, the time needed to recover from repeat doses does not change with additional doses, suggested maintenance dose of 0.08 to 0.10 mg/kg is required within 20 to 45 minutes and subsequent doses with 15 – 25 minutes interval. Recovery from neuromuscular block (under balanced anaesthesia) can be expected to begin approximately 20 to 35 minutes after injection. The neuromuscular blocking action of Acuron (Atracurium Besylate) is enhanced in the presence of potent inhalation anaesthetics. Reversal of neuromuscular block produced by Atracurium Besylate can be achieved with an anticholinesterase agent such as neostigmine, edrophonium, or pyridostigmine, in conjunction with an anticholinergic agent such as atropine or glycopyrrolate.

The pharmacokinetics of Acuron (Atracurium Besylate) is essentially linear within 0.3 to 0.6 mg/kg dose range.The duration of neuromuscular blockade produced by Acuron does not correlate with plasma pseudocholinesterase level and is not altered in compromised renal function. The elimination half life is approx. 20 minutes. Acuron (Atracurium Besylate) is inactivated in plasma via two non-oxidation pathways esterase's and Hoffman elimination, a non-enzymatic chemical process.

Indications:
- As an adjunct to General Anaesthesia.
- To facilitate endotracheal intubation.
- To provide skeletal muscle relaxation during surgery or ventilation.

Dosage and Administration:
To avoid distress to the patients, Acuron (Atracurium Besylate) should not be administered before unconsciousness has been induced. Acuron(Atracurium Besylate) should not be mixed in the same syringe with alkaline solutions.

Adults:
Acuron (Atracurium Besylate) Injection in a dose of 0.4 to 0.5 mg/kg given as an intravenous bolus injection, is the recommended initial dose for most patients. With this dose, non-emergency intubations can be expected in 2 to 2.5 minutes in most patients, with maximum neuromuscular block achieved approximately 3 to 5 minutes after injection. Acuron Injection is potentiated by inhalational anaesthetics.

Maintenance Dose:
Acuron (Atracurium Besylate) in doses of 0.08 to 0.10 mg/kg are recommended for maintenance of neuromuscular block during prolonged surgical procedures. The first maintenance dose will generally be required 20 to 45 minutes after the initial Injection, but the need for maintenance doses should be determined by clinical criteria.

Pediatric (Children/Infants) Patients:
Acuron (Atracurium Besylate) in a dose of 0.3 to 0.4 mg/kg is recommended as the initial dose for infants (1 month to 2 years of age) under halothane anaesthesia. Maintenance doses may be required with slightly greater frequency in infants and children than in adults. No dosage adjustments are required for pediatric patients 2 years of age or older.

Dosage Under Special Conditions:
Acuron (Atracurium Besylate) in a dose of 0.3 to 0.4 mg/kg, given slowly or in divided doses over one minute, is recommended for adults, adolescents, children, or infants with significant cardiovascular disease and severe anaphylactoid reactions or asthma suggesting a greater risk of histamine release. Dosage reductions must be considered in patients with neuromuscular disease, severe electrolyte disorders, or carcinomatosis in which potentiation of neuromuscular block or difficulties with reversal have been demonstrated.

Dosage by Continuous Infusion in OT & ICU's:
After administration of a recommended initial bolus dose of Acuron (Atracurium Besylate) in a dose of 0.3 to 0.5 mg/kg, a diluted solution of Acuron (Atracurium Besylate) can be administered by continuous infusion to adults and pediatric patients aged 2 or more years for maintenance of neuromuscular block during extended surgical procedures and in ICU's.

Infusion should be individualized for each patient. The rate of administration should be adjusted according to the patient's response as determined by peripheral nerve stimulation.

An initial infusion rate of 9 to 10 mcg/kg per minute may be required to rapidly counteract the spontaneous recovery of neuromuscular function. Thereafter, a rate of 5 to 9 mcg/kg per minute should be adequate to maintain continuous neuromuscular block.

Occasional patients may require infusion rates as low as mcg/kg per minute or as high as 15 mcg/kg per minute.

The rate of Atracurium Besylate Injection infusion should be reduced by approximately one third in the presence of inhalation anaesthetics.

Contraindications:
Acuron (Atracurium Besylate) is contraindicated in patients known to have a hypersensitivity to it.

Side Effects:
Acuron is well tolerated and produce little adverse reaction during extensive clinical trials.

General – Allergic reactions (anaphylactic or anaphylactoid response).
CNS – hypotension, vasodilation, tachycardia, bradycardia.
Respiratory - Dyspnoea, bronchospasm, laryngospasm.
Skin – Rash, urticaria.

Precautions:
Acuron (Atracurium Besylate) is a less potent histamine releaser than d-tubocurarine or metocurine, Special caution should be exercised in administering Acuron (Atracurium Besylate) to

patients with significant cardiovascular disease and in patients with any history severe anaphylactoid reactions or asthma, suggesting a greater risk of histamine release.

Since Acuron (Atracurium Besylate) has no clinically significant effects on heart rate in the recommended dosage range as a result, bradycardia during anaesthesia may be more common with Acuron (Atracurium Besylate) than with other muscle relaxants.

Acuron (Atracurium Besylate) may have profound effects in patients with myasthenia gravis, Eaton-Lambert syndrome, or other neuromuscular diseases in which potentiation of non-depolarizing agents has been noted. The use of a peripheral nerve stimulator is especially important for assessing neuromuscular block in these patients. Similar precautions should be taken in patients with severe electrolyte disorders or carcinomatosis.

Hemofiltration has a minimal effect on plasma levels of atracurium and its metabolites, including audanosine. The effects of hemodialysis and hemoperfusion on plasma levels of Acuron (Atracurium Besylate) and its metabolites are unknown.

Warnings:
Acuron (Atracurium Besylate) should be used only by those skilled in airway management and respiratory support. Equipment and personnel must be immediately available for endotracheal intubation and support of ventilation, including administration of positive pressure oxygen. Anticholinesterase reversal agents should be immediately available. Do not give Acuron (Atracurium Besylate) Injection by intramuscular administration.

Acuron (Atracurium Besylate), which has an acidic pH, should not be mixed with alkaline solutions (e.g., barbiturate solutions) in the same syringe or administered simultaneously during intravenous infusion through the same needle.

Use in Special Situations:
Acuron (Atracurium Besylate) is Pregnancy Category C. No harmful effects were attributable to Acuron (Atracurium Besylate) Injection in any of the neonates, although small amounts of Atracurium Besylate were shown to cross the placental barrier, It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Acuron (Atracurium Besylate) is administered to a nursing woman.

Over Dosage:
There has been limited experience with Acuron (Atracurium Besylate) overdosage. The possibility of iatrogenic overdosage can be minimized by carefully monitoring muscle twitch response to peripheral nerve stimulation. Excessive doses of Acuron (Atracurium Besylate) can be expected to produce enhanced pharmacological effects. Over dosage may increase the risk of histamine release and cardiovascular effects, especially hypotension.

Storage:
Store in refrigerator at 2-8°C. DO NOT FREEZE. Upon removal from refrigerator to room temperature storage conditions (25°C), use Acuron (Atracurium Besylate) within 14 days even if re-refrigerated.

Presentation:
Acuron (Atracurium Besylate) Injection IV is available in 5x3ml (30mg/Ampoule) and 5x5ml (50mg/Ampoule) Packs.

خوراک اور طریقہ استعمال:

بالغ:

تجویز کردہ بنیادی خوراک کی مقدار 0.4 سے 0.5 ملی گرام/کلوگرام بطور وریدی انجکشن ہے۔

تجویز کردہ خوراک کی مقدار 0.08 سے 0.10 ملی گرام/کلوگرام ہے جو کہ نیورومسکولر بلاک کو طویل جراحی کے درمیان قائم رکھتی ہے۔

پہلی خوراک کی ضرورت عموماً بنیادی مقدار ملنے کے 20 سے 45 منٹ کے بعد دینی ہوتی ہے اور متواتر خوراک کے لیے طبی معائنہ ایک لازمی جز ہے۔

بچے:

دو سال یا دو سال سے بڑے بچوں کے لیے خوراک کی ہم آہنگی کی ضرورت نہیں۔

1 ماہ سے 2 سال تک کی عمر کے لیے 0.3 سے 0.4 ملی گرام/کلوگرام تجویز کردہ خوراک ہے۔

بالغ میں بذریعہ انفیوژن استعمال:

بنیادی خوراک 0.3 سے 0.5 ملی گرام/کلوگرام جسمانی وزن کے مطابق ایکیوورون (ایٹراکیریم بی سائیلیٹ) کو نیورومسکولر بلاک کو قائم رکھنے کے لیے طویل جراحی کے لیے اسی مقدار سے استعمال کیا جاسکتا ہے۔

اسٹوریج:

2 تا 8 ڈگری سینٹی گریڈ پر ریفریجریٹر میں رکھیے۔ منجمد ہونے سے بچایئے۔ ریفریجریٹر سے نکالنے کے بعد کمرے کے درجہ حرارت (25 ڈگری سینٹی گریڈ) پر لانے اور دوبارہ ریفریجریٹر میں رکھنے کی صورت میں 14 دن کے اندر استعمال کر لیجیے۔

brookes

Manufactured by:

Brookes Pharma Private Limited
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Karachi 74900 Pakistan.

ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification

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