PRESCRIBING INFORMATION

CIS-CURON Injection (IV)

(Cis-atracurium Besylate Injection USP)

سسکیوران انجکشن (آئی وی)

Composition:
Each ml contains
Cis-atracurium.....2mg
(as Cis-atracurium Besylate.....Brookes Specs)

DESCRIPTION

Cis-Curon (cis-atracurium besylate Injection USP) is a nondepolarizing skeletal muscle relaxant for intravenous administration. It is intermediate in its onset and duration of action. Cis-atracurium besylate Injection USP is one of 10 isomers of atracurium besylate and constitutes approximately 15% of that mixture.

CLINICAL PHARMACOLOGY

Pharmacodynamics:
Cisatracurium, a stereoisomer of atracurium, is an intermediate duration, non-depolarising benzylisoquinolinium skeletal muscle relaxant. Cisatracurium besylate binds to cholinergic receptors on the motor end-plate to antagonise the action of acetylcholine, resulting in a competitive block of neuromuscular transmission. This action is readily reversed by anticholinesterase agents such as neostigmine.
Pharmacokinetics in Adult patients:
Non-compartmental pharmacokinetics of cisatracurium besylate are independent of dose in the range studied (0.1 to 0.2 mg/kg bodyweight; ie. 2 to 4 x ED_{95}).
Pharmacokinetics during infusions:
The pharmacokinetics of cisatracurium besylate following infusion of Cis-Curon Injection are similar to those following a single bolus injection.
Pharmacokinetics in Intensive Care Unit (ICU) patients:
The pharmacokinetics of cisatracurium besylate in ICU patients receiving prolonged infusion are similar to those in healthy surgical adults receiving infusion or single bolus injection.
Pharmacokinetics in elderly patients:
There are no clinically important differences in the pharmacokinetics of cisatracurium besylate in elderly patients.
Pharmacokinetics in paediatric patients:
No full study has been performed to assess the pharmacokinetics of cisatracurium in paediatric patients.
Pharmacokinetics in patients with renal impairment:
There are no clinically important differences in the pharmacokinetics of cisatracurium besylate in patients with end-stage renal failure.
Pharmacokinetics in patients with hepatic impairment:
There are no clinically important differences in the pharmacokinetics of cisatracurium besylate in patients with end-stage liver disease.

INDICATIONS

- As an adjunct to general anaesthesia.
- To facilitate non-emergency endotracheal intubation.
- To provide skeletal muscle relaxation during surgery or mechanical ventilation.

CONTRAINDICATIONS

Cis-Curon Injection is contraindicated in patients known to be hypersensitive to cisatracurium besylate, atracurium besylate or benzenesulfonic acid

Use in Pregnancy
Pregnancy Category: C
Teratological studies in non-ventilated pregnant rats treated subcutaneously with maximum subparalysing doses (4 mg/kg daily) and in ventilated rats treated intravenously with paralyzing doses of cisatracurium (1.0 mg/kg), respectively, revealed no fetal toxicity or teratogenic effects.
Use in lactation:
Studies have not been conducted to determine whether cisatracurium or its metabolites are excreted in human or animal milk.
Adverse reactions:
No adverse experiences considered to be reasonably attributable to Cis-Curon Injection
Cardiovascular: Bradycardia (0.4%), hypotension (0.2%), flushing (0.2%).
Respiratory: Bronchospasm (0.2%).
Dermatological: Rash (0.1%).
Hypersensitivity:
Very rarely: Severe anaphylactic reactions have been reported in patients receiving Cis-Curon Injection in conjunction with one or more anaesthetic agents.

DOSAGE AND ADMINISTRATION

Cis-Curon Injection contains no antimicrobial preservative and is intended for single patient use.

USE BY INTRAVENOUS BOLUS INJECTION

Dosage in Adults:Tracheal intubation. The recommended intubation dose of Cis-Curon Injection for adults is 0.15 mg/kg bodyweight.
Maintenance:A dose of 0.03 mg/kg bodyweight provides approximately 20 minutes of additional clinically effective neuromuscular block during opioid or propofol anaesthesia.
Spontaneous recovery: During opioid or propofol anaesthesia the median times from 25 to 75% and from 5 to 95% recovery are approximately 13 and 30 minutes respectively.
Reversal: Neuromuscular block following the administration of Cis-Curon Injection is readily reversible with standard doses of anticholinesterase agents.
Dosage in Paediatric Patients ages 1 month to 12 years:
Tracheal Intubation: As in adults, the recommended intubation dose of Cis-Curon Injection is 0.15 mg/kg bodyweight administered rapidly over 5 to 10 seconds.
Use by intravenous infusion:
Dosage in Adults and Paediatric Patients aged 1 month to 12 years:
An initial infusion rate of 3 µg/kg/min (0.18 mg/kg/hr) is recommended to restore 89 to 99% T_1 suppression following evidence of spontaneous recovery.
Dosage in neonates aged less than 1 month:
Cis-Curon Injection has not been studied in this patient population.
Dosage in Intensive Care Unit (ICU) patients:
An initial infusion rate of Cis-Curon Injection of 3 µg/kg/min (0.18 mg/kg/hr) is recommended.
Dosage in elderly patients:
No dosing alterations are required in elderly patients. In these patients Cis-Curon Injection has a similar pharmacodynamic profile to that observed in young adult patients; however, as with other neuromuscular blocking agents, it may have a slightly slower onset.
Dosage in patients with renal impairment:
No dosing alterations are required in patients with renal failure.
Dosage in patients with hepatic impairment:
No dosing alterations are required in patients with end-stage liver disease.
Patients with cardiovascular disease:
Cis-Curon Injection has not been associated with clinically significant cardiovascular effects at any dose studied (up to and including 0.4 mg/kg (8 x ED95)).

Dosage in patients undergoing hypothermic cardiac surgery:
There have been no studies of Cis-Curon Injection in patients undergoing surgery with induced hypothermia (25° to 28°C). As with other neuromuscular blocking agents, the rate of infusion required to maintain adequate surgical relaxation under these conditions may be expected to be significantly reduced.

MONITORING
As with other neuromuscular blocking agents, monitoring of neuromuscular function is recommended during the use of Cis-Curon Injection in order to individualize dosage requirements.

INSTRUCTIONS OF USE
Physical Compatibilities:
Diluted Cis-Curon Injection is chemically and physically stable for at least 12 hours, when stored in either polyvinyl chloride or polypropylene containers, at concentrations between 0.1 and 2.0 mg/mL in the following infusion solutions:
Sodium Chloride (0.9% w/v) Intravenous Infusion
Glucose (5% w/v) Intravenous Infusion
Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion
Sodium Chloride (0.45% w/v) and Glucose (2.5% w/v) Intravenous Infusion

OVERDOSAGE
Symptoms and signs:
Prolonged muscle paralysis and its consequences are expected to be the main signs of overdose with Cis-Curon Injection.

MANAGEMENT
It is essential to maintain pulmonary ventilation and arterial oxygenation until adequate spontaneous respiration returns. Full sedation will be required since consciousness is not impaired by Cis-Curon Injection. Recovery may be accelerated by the administration of anticholinesterase agents once evidence of spontaneous recovery is present.

PRESENTATION
Cis-Curon Injection is available in the following pack sizes:
Cis-Curon Injection 2 mg/mL: 5 x 5 mL Ampoules

STORAGE
Store in refrigerator at 2 to 8ºC. DO NOT FREEZE.
Upon removal from refrigeration to room temperature, storage conditions (25ºC). Use CIS-CURON Injection within 14 days even if re-refrigerated.

مقدار اور طریقہ استعمال:

بالغ:

تجویز کردہ بنیادی مقدار 0.15 ملی گرام/کلوگرام بطور وریدی انجکشن ہے۔
تجویز کردہ مقدار 0.03 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 منٹ کے بعد دینی ہوتی ہے اور متواتر خوراک کے لئے طبی معائنہ ایک لازمی جز ہے۔

بچے:

دو سال یا دو سال سے بڑے بچوں کے لئے خوراک کی ہم آہنگی کی ضرورت نہیں۔
1 ماہ سے 12 سال تک کی عمر کے لئے 0.15 ملی گرام/کلوگرام تجویز کردہ مقدار ہے۔

بالغ بذریعہ انفیوژن استعمال:

بنیادی مقدار 0.18 ملی گرام/کلوگرام فی گھنٹہ جسمانی وزن کے مطابق سسکیوران کو نیورومسکولر بلاک قائم رکھنے کے لئے طویل جراحی کے لیئے اسی مقدار سے استعمال کیا جاسکتا ہے۔

اسٹوریج:

2 تا 8 ڈگری سینٹی گریڈ پر ریفریجریٹر میں رکھیئے۔ 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 لیجیئے۔

brookes

Manufactured by:

Brookes Pharma Private Limited
58 - 59 Sector 15 Korangi Industrial Area
Karachi 74900 Pakistan.

ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification

1309-00158-1001