CISATRACURIUM KABI 2MG/ML SOLUTION FOR INJECTION OR INFUSION

COMPOSITION
1 ml solution for injection/infusion contains 2.68 mg cisatracurium besilate equivalent to 2 mg cisatracurium.
1 ampoule of 2.5 ml solution for injection/infusion contains 6.7 mg cisatracurium besilate equivalent to 5 mg cisatracurium.
1 ampoule of 5 ml solution for injection/infusion contains 13.4 mg cisatracurium besilate equivalent to 10 mg cisatracurium.
1 ampoule of 10 ml solution for injection/infusion contains 26.8 mg cisatracurium besilate equivalent to 20 mg cisatracurium.

PHARMACEUTICAL FORM
Solution for injection or infusion.
Clear, colourless to pale yellow or greenish yellow solution.
Cisatracurium Kabi 2 mg/ml solution for injection or infusion may be diluted in sodium chloride 9 mg/ml (0.9 %) solution; in sodium chloride 9 mg/ml (0.9 %) and glucose 50 mg/ml (5 %) solution; and in glucose 50 mg/ml (5 %) solution.
The diluted solution should be clear and colourless or almost colourless up to slightly yellow/greenish yellow, practically free from particles.

THERAPEUTIC INDICATIONS
Cisatracurium Kabi 2 mg/ml solution for injection or infusion is an intermediate-duration, non-polarising neuromuscular blocking agent for intravenous administration. Cisatracurium Kabi 2 mg/ml solution for injection or infusion is indicated for use during surgical and other procedures and in intensive care. It is used as an adjunct to general anaesthesia, or sedation in the intensive care unit (ICU), to relax skeletal muscles, and to facilitate tracheal intubation and mechanical ventilation. Cisatracurium Kabi 2mg/ml solution for injection or infusion contains no microbial preservative and is intended for single patient use.

POSOLOGY AND METHOD OF ADMINISTRATION
Cisatracurium Kabi 2mg/ml solution for injection or infusion should only be administered by or under the supervision of anaesthetists or other clinicians who are familiar with the use and action of neuromuscular blocking agents. Facilities for tracheal intubation and maintenance of pulmonary ventilation and adequate arterial oxygenation have to be available. Monitoring of neuromuscular function is recommended during the use of Cisatracurium Kabi in order to individualise dosage requirements.

Posology
- Use by intravenous bolus injection

Dosage in adults
Endotracheal Intubation
The recommended intubation dose of cisatracurium for adults is 0.15 mg/kg (body weight). Endotracheal intubation can be accomplished 120 seconds after administration of Cisatracurium Kabi, following induction of anaesthesia with propofol.
Higher doses will shorten the time to onset of neuromuscular block.

The following table summarises mean pharmacodynamic data when cisatracurium was administered at doses of 0.1 to 0.4 mg/kg (body weight) to healthy adult patients during opioid (thiopentone/fentanyl/midazolam) or propofol anaesthesia.

Initial cisatracurium dose (mg/kg bw)	Anaesthetic Background	Time to 90 % T_1* Suppression (min)	Time to Maximum T_1* Suppression (min)	Time to 25 % Spontaneous T_1* Recovery (min)
0.1	Opioid	3.4	4.8	45
0.15	Propofol	2.6	3.5	55
0.2	Opioid	2.4	2.9	65
0.4	Opioid	1.5	1.9	91

* T_1 Single twitch response as well as the first component of the Train-of-four response of the adductor pollicis muscle following supramaximal electrical stimulation of the ulnar nerve.

Enflurane or isoflurane anaesthesia may extend the clinically effective duration of an initial dose of cisatracurium by up to 15 %.

Maintenance
Neuromuscular block can be extended with maintenance doses of cisatracurium. A dose of 0.03 mg/kg (body weight) provides approximately 20 minutes of additional clinically effective neuromuscular block during opioid or propofol anaesthesia.

Successive supplementary dosing does not produce accumulation in neuromuscular blocking effect.

Spontaneous Recovery
Once evidence of spontaneous recovery from neuromuscular block is present, the duration until complete reversal is independent of the cisatracurium dose administered. During opioid or propofol anaesthesia, the mean duration for recovery from 25 to 75 % and from 5 to 95 % is approximately 13 and 30 minutes, respectively.

Reversal
Neuromuscular block following cisatracurium administration is readily reversible with standard doses of anticholinesterase agents. The mean duration of recovery from 25 to 75 % and to full clinical recovery (T4:T1 ratio $\geq$ 0.7) is approximately 4 and 9 minutes, respectively, following administration of the reversal agent at an average T1 recovery of 10 %.

Dosage in paediatric population
Endotracheal Intubation (paediatric patients aged 1 month to 12 years)
As in adults, the recommended intubation dose of cisatracurium is 0.15 mg/kg (body weight) administered rapidly over 5 to 10 seconds. Endotracheal intubation can be accomplished 120 seconds after administration of cisatracurium.
Pharmacodynamic data for this dose are presented in the tables below.

Cisatracurium has not been studied for intubation in ASA Class III-IV paediatric patients. There are limited data on the use of cisatracurium in paediatric patients under 2 years of age undergoing prolonged or major surgery.
In paediatric patients aged 1 month to 12 years, cisatracurium has a shorter clinically effective duration and a faster spontaneous recovery profile than those observed in adults under similar anaesthetic conditions. Small differences in the pharmacodynamic profile were observed between the age ranges 1 to 11 months and 1 to 12 years which are summarised in the tables below.

Paediatric Patients aged 1 to 11 months

Cisatracurium Dose mg/kg (body weight)	Anaesthetic Background	Time to 90 % Suppression (min)	Time to Maximum Suppression (min)	Time to 25 % Spontaneous T_1* Recovery (min)
0.15	Halothane	1.4	2.0	52
0.15	Opioid	1.4	1.9	47

Paediatric Patients aged 1 to 12 years

Cisatracurium Dose mg/kg (body weight)	Anaesthetic Background	Time to 90 % Suppression (min)	Time to Maximum Suppression (min)	Time to 25 % Spontaneous T_1* Recovery (min)
0.15	Halothane	2.3	3.0	43
0.15	Opioid	2.6	3.6	38

When cisatracurium is not required for intubation: A dose of less than 0.15 mg/kg can be used. Pharmacodynamic data for doses of 0.08 and 0.1 mg/kg for paediatric patients aged 2 to 12 years are presented in the table below:

Cisatracurium Dose mg/kg (body weight)	Anaesthetic Background	Time to 90 % Suppression (min)	Time to Maximum Suppression (min)	Time to 25 % Spontaneous T_1* Recovery (min)
0.08	Halothane	1.7	2.5	31
0.1	Opioid	1.7	2.8	28

Administration of cisatracurium following suxamethonium has not been studied in paediatric patients (see section Interaction with other medicinal product).
Halothane may extend the clinically effective duration of a dose of cisatracurium by up to 20 %.

No information is available on the use of cisatracurium in children during anaesthesia with other halogenated fluorocarbon anaesthetic agents. Nevertheless, these agents may also be expected to extend the clinically effective duration of a cisatracurium dose.

Maintenance (paediatric patients aged 2-12 years)
Neuromuscular block can be extended with maintenance doses of cisatracurium. In paediatric patients aged 2 to 12 years, a dose of 0.02 mg/kg (body weight) provides approximately 9 minutes of additional clinically effective neuromuscular block during halothane anaesthesia.
Successive supplementary dosing does not produce accumulation in neuromuscular blocking effect.
There are insufficient data available for recommendation of maintenance dosing in paediatric patients under 2 years of age. However, very limited data from clinical studies in paediatric patients under 2 years of age suggest that a maintenance dose of 0.03 mg/kg may extend clinically effective neuromuscular block for a period of up to 25 minutes during opioid anaesthesia.

Spontaneous Recovery
Once evidence of spontaneous recovery from neuromuscular block is present, the duration until complete reversal is independent of the cisatracurium dose administered. During opioid or halothane anaesthesia, the mean duration for recovery from 25 to 75 % and from 5 to 95 % are approximately 11 and 28 minutes, respectively.

Reversal
Neuromuscular block following cisatracurium administration is readily reversible with standard doses of anti-cholinesterase agents. The mean duration of recovery from 25 to 75 % and to full clinical recovery (T4:T1 ratio $\geq$ 0.7) are approximately 2 and 5 minutes respectively, following administration of the reversal agent at an average T1 recovery of 13 %.

- Use by intravenous infusion

Dosage in adults and children aged 2 to 12 years
Maintenance of neuromuscular block is achieved by infusion of Cisatracurium Kabi. Following evidence of spontaneous recovery, an initial infusion rate of 3 µg/kg/min (0.18 mg/kg/h) is recommended to restore 89 to 99 % T_1 suppression. After a primary stabilisation period of the neuromuscular block, an infusion rate of 1 to 2 µg/kg/min (0.06 to 0.12 mg/kg/h) should be adequate to maintain block in this range in most patients. Reduction of the infusion rate by up to 40 % may be required when cisatracurium is administered during isoflurane or enflurane anaesthesia (see section Interaction with other medicinal product).
The infusion rate depends on the concentration of cisatracurium in the infusion solution, the desired degree of neuromuscular block, and the patient's body weight. The following table provides guidelines for infusion of undiluted Cisatracurium Kabi.

Infusion Rate of Cisatracurium Kabi:

Patient (body weight) (kg)	Dose (µg/kg/min)				Infusion Rate
	1.0	1.5	2.0	3.0	
20	0.6	0.9	1.2	1.8	ml/h
70	2.1	3.2	4.2	6.3	ml/h
100	3.0	4.5	6.0	9.0	ml/h

Steady rate continuous infusion is not associated with a progressive increase or decrease in neuromuscular blocking effect.
Following termination of infusion, spontaneous recovery from neuromuscular block proceeds at a rate comparable to that following administration of a single bolus injection.
- Use by intravenous bolus injection and/or by intravenous infusion

Dosage in adults
Intensive Care Unit (ICU) patients
Cisatracurium Kabi may be administered by bolus dose and/or infusion to adult patients in the ICU.
An initial infusion rate of 3 µg/kg/min (0.18 mg/kg/h) is recommended for adult ICU patients. There may be wide interpatient variation in dosage requirements, and these may increase or decrease with time. In clinical studies the average infusion rate was 3 µg/kg/min [range 0.5 to 10.2 µg/kg (body weight)/min (0.03 to 0.6 mg/kg/h)].
The mean duration to full spontaneous recovery following long-term (up to 6 days) infusion of cisatracurium in ICU patients was approximately 50 minutes.
The recovery profile after infusions of cisatracurium to ICU patients is independent of the duration of the infusion.

Special populations
Dosage in new-born infants (aged less than 1 month)
The use of cisatracurium in new-born infants is not recommended as it has not been studied in this patient population.

Dosage in elderly patients
No dosing alterations are required in elderly patients. In these patients a pharmacodynamic profile similar to young adult patients is observed but, as with other neuromuscular blocking agents, a delayed onset might occur.

Dosage in patients with renal impairment
No dosing alterations are required in patients with renal failure.
In these patients a similar pharmacodynamic profile to that in patients with normal renal function is observed but a delayed onset might occur.

Dosage in patients with hepatic impairment
No dosing alterations are required in patients with end-stage liver disease. In these patients a similar pharmacodynamic profile to that in patients with normal hepatic function is observed but a slightly accelerated onset might occur.

Dosage in patients with cardiovascular disease
When administered by rapid bolus injection (over 5 to 10 seconds) to adult patients with serious cardiovascular disease (New York Heart Association Class I-III) undergoing coronary artery bypass graft (CABG) surgery, cisatracurium has not been associated with clinically significant cardiovascular effects at any dose studied (maximal 0.4 mg/kg (8 x ED95). However, there are limited data for doses above 0.3 mg/kg bw in this patient population.
Cisatracurium has not been studied in children undergoing cardiac surgery.

Method of administration
Cisatracurium Kabi is an intermediate-duration, non-depolarising neuromuscular blocking agent for intravenous administration.
Cisatracurium Kabi contains no antimicrobial preservative and is intended for single dose use only.
The product should be visually inspected prior to use. The solution should only be used if it is clear and colourless or almost colourless up to slightly yellow/greenish yellow, practically free from particles and if the container is undamaged. If the visual appearance has changed or if the container is damaged, the product must be discarded.

CONTRAINDICATIONS
Hypersensitivity to cisatracurium, atracurium or benzenesulfonic acid

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Product specific topics
Cisatracurium paralyses the respiratory muscles as well as other skeletal muscles but has no known effect on consciousness or pain threshold.
Caution should be exercised when administering cisatracurium to patients who have shown hypersensitivity to other neuromuscular blocking agents since a high rate of cross-sensitivity (greater than 50 %) between neuromuscular blocking agents has been reported.

Cisatracurium does not have significant vagolytic or ganglion- blocking properties. Consequently, cisatracurium has no clinically significant effect on heart rate and will not counteract the bradycardia produced by many anaesthetic agents or by vagal stimulation during surgery.

Patients with myasthenia gravis and other forms of neuromuscular disease have shown greatly increased sensitivity to non-depolarising blocking agents. An initial dose of not more than 0.02 mg/kg is recommended in these patients.

There is no information on the use of cisatracurium in new-born infants aged less than one month since it has not been studied in this patient population.

Cisatracurium has not been studied in patients with a history of malignant hyperthermia. Studies in malignant hyperthermia-susceptible pigs indicated that cisatracurium does not trigger this syndrome.

There have been no studies of cisatracurium in patients undergoing surgery with induced hypothermia (25 to 28 °C). The rate of infusion required to maintain adequate surgical relaxation under these conditions may be expected to be significantly reduced.

Cisatracurium has not been studied in patients with burns; however, the possibility of increased dosing requirements and shortened duration of action must be considered if cisatracurium is administered to these patients.

Cisatracurium Kabi is hypotonic and must not be applied into the infusion line of a blood transfusion.

Intensive Care Unit (ICU) Patients
When administered to laboratory animals in high doses, laudanosine, a metabolite of cisatracurium and atracurium, has been associated with transient hypotension and in some species, cerebral excitatory effects. In the most sensitive animal species, these effects occurred at laudanosine plasma concentrations similar to those that have been observed in some ICU patients following prolonged infusion of atracurium. Consistent with the decreased infusion rate requirements of cisatracurium, plasma laudanosine concentrations are approximately one third those following atracurium infusion.

There have been rare reports of seizures in ICU patients who have received atracurium and other agents. These patients usually had one or more medical conditions predisposing to seizures (e.g. cranial trauma, hypoxic encephalopathy, cerebral oedema, viral encephalitis, uraemia). A causal relationship to laudanosine has not been established.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Many medicinal products have been shown to influence the magnitude and/or duration of action of non-depolarising neuromuscular blocking agents, including the following:

Increased Effect:
- by anaesthetic agents such as enflurane, isoflurane, halothane (see section 4.2) and ketamine,
- by other non-depolarising neuromuscular blocking agents,
- by other medicinal products such as antibiotics (including the aminoglyco-sides, polymyxins, spectinomycin, tetracyclines, lincomycin and clindamycin),
- by antiarrhythmics (including propranolol, calcium channel blockers, lidocaine, procainamide and quinidine),
- by diuretics, (including furosemide and possibly thiazides, mannitol and acetazolamide),
- by magnesium and lithium salts and
- by ganglion blocking agents (trimetaphan, hexamethonium).

A decreased effect is seen after preceding chronic administration of phenytoin or carbamazepine. Preceding administration of suxamethonium has no effect on the duration of neuromuscular block following bolus doses of cisatracurium or on infusion rate requirements.

Administration of suxamethonium to prolong the effects of non-depolarising neuromuscular blocking agents may result in a prolonged and complex block which can be difficult to reverse with anticholinesterases.

Rarely, certain medicinal products may aggravate or unmask latent myasthenia gravis or actually induce a myasthenic syndrome; increased sensitivity to nondepolarizing neuromuscular blocking agents might result. Such agents include various antibiotics, betablockers (propranolol, oxprenolol), antiarrhythmics (procainamide, quinidine), antirheumatics (chloroquine, D-penicillamine), trimetaphan, chlorpromazine, steroids, phenytoin and lithium.

Treatment with anticholinesterases, commonly used in the treatment of Alzheimer's disease e.g. donepezil, may shorten the duration and diminish the magnitude of neuromuscular blockade with cisatracurium.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy
There are no adequate data from the use of cisatracurium in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonic/foetal development, parturition and postnatal development (see section 5.3). The potential risk for humans is unknown.

Cisatracurium Kabi should not be used during pregnancy.

Lactation
It is not known whether cisatracurium or its metabolites are excreted in human milk.
A risk to the suckling child cannot be excluded. However, due to the short half-life, an influence on the breastfed infant is not to be expected if the mother restarts breast-feeding after the effects of the substance have worn off. As a precaution, breast-feeding should be discontinued during treatment and it is recommended to abstain from next breastfeeding for five elimination half- lives of cisatracurium, i.e. for about 3 hours after the last dose or the end of infusion of cisatracurium.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
Cisatracurium Kabi as all other anaesthetics can have major influence on the ability to drive or use machines. The patient must not drive or operate machines following anaesthesia with cisatracurium.
The time factor should be decided individually by the physician.

UNDESIRABLE EFFECTS
Immune system Disorders:
Very rare: Anaphylactic reactions, Anaphylactic shock.
Anaphylactic reactions of varying degrees of severity have been observed after the administration of neuromuscular blocking agents, including anaphylactic shock. Very rarely, severe anaphylactic reactions have been reported in patients receiving cisatracurium in conjunction with one or more anaesthetic agents.

Cardiac Disorders:
Common: Bradycardia

Vascular Disorders:
Common: Hypotension
Uncommon: Cutaneous flushing

Respiratory, Thoracic and Mediastinal Disorders:
Uncommon: Bronchospasm

Skin and subcutaneous tissue Disorders:
Uncommon: Rash

Musculoskeletal and connective Tissue Disorders:
Very rare: Myopathy, muscle weakness

There have been some reports of muscle weakness and/or myopathy following prolonged use of muscle relaxants in severely ill patients in the ICU. Most patients were receiving concomitant corticosteroids. These events have been reported infrequently in association with cisatracurium and a causal relationship has not been established.

SYMPTOMS AND TREATMENT OF OVERDOSE
Symptoms and signs
Prolonged muscle paralysis and its consequences are expected to be the main signs of overdose with cisatracurium.

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 cisatracurium. Recovery may be accelerated by the administration of anti-cholinesterase agents once evidence of spontaneous recovery is present.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: Muscle relaxants, peripherally acting agents; other quaternary ammonium compound.
ATC code: M03AC11

Cisatracurium is an intermediate-duration, non-depolarising benzylisoquinolinium skeletal muscle relaxant.

Clinical studies in man indicated that cisatracurium is not associated with dose dependent histamine release even at doses up to and including 8 x ED95.

Mechanism of action
Cisatracurium 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 or edrophonium.

The ED_{95} (dose required to produce 95 % depression of the twitch response of the adductor pollicis muscle to stimulation of the ulnar nerve) of cisatracurium is estimated to be 0.05 mg/kg bodyweight during opioid anaesthesia (thiopentone/fentanyl/midazolam).

The ED_{95} of cisatracurium in children during halothane anaesthesia is 0.04 mg/kg.

Pharmacokinetic properties
Cisatracurium undergoes degradation in the body at physiological pH and temperature by Hofmann elimination (a chemical process) to form laudanosine and the monoquaternary acrylate metabolite. The monoquaternary acrylate undergoes hydrolysis by non-specific plasma esterases to form the monoquaternary alcohol metabolite. Elimination of cisatracurium is largely organ independent but the liver and kidneys are primary pathways for the clearance of its metabolites.

These metabolites do not possess neuromuscular blocking activity.

Pharmacokinetics in adult patients
Non-compartmental pharmacokinetics of cisatracurium are independent of dose in the range studied (0.1 to 0.2 mg/kg, i.e. 2 to 4 x ED_{95}).

Population pharmacokinetic modelling confirms and extends these findings up to 0.4 mg/kg (8 x ED_{95}). Pharmacokinetic parameters after doses of 0.1 and 0.2 mg/kg cisatracurium administered to healthy adult surgical patientsare summarised in the table below:

Parameter	Range of Mean Values
Clearance	4.7 to 5.7 ml/min/kg
Volume of distribution at steady state	121 to 161 ml/kg
Elimination half-life	22 to 29 min

Pharmacokinetics in elderly patients
There are no clinically important differences in the pharmacokinetics of cisatracurium in elderly and young adult patients. The recovery profile is also unchanged.

Pharmacokinetics in patients with renal/hepatic impairment
There are no clinically important differences in the pharmacokinetics of cisatracurium in patients with end- stage renal failure or end stage liver disease and in healthy adult patients. Their recovery profiles are also unchanged.

Pharmacokinetics during infusions
The pharmacokinetics of cisatracurium after infusions of cisatracurium are similar to those after single bolus injection. The recovery profile after infusion of cisatracurium is independent of duration of infusion and is similar to that after single bolus injection.

Pharmacokinetics in Intensive Care Unit (ICU) patients
The pharmacokinetics of cisatracurium in ICU patients receiving prolonged infusions are similar to those in healthy surgical adults receiving infusions or single bolus injections. The recovery profile after infusions of cisatracurium in ICU patients is independent of duration of infusion.

Concentrations of metabolites are higher in ICU patients with abnormal renal and/or hepatic function (see section 4.4). These metabolites do not contribute to neuromuscular block.

PHARMACEUTICAL PARTICULARS
List of excipients
Benzenesulfonic acid 1 % (for pH-adjustment)
Water for injections

INCOMPATIBILITIES
This medicinal product must not be mixed with other medicinal products except those mentioned in section Special Precaution for Disposal and Handling.

Since cisatracurium is stable only in acidic solutions it should not be mixed in the same syringe or administered simultaneously through the same needle with alkaline solutions, e.g., sodium thiopentone.

It is not compatible with ketorolac trometamol or propofol injectable emulsion.

SHELF LIFE
Unopened ampoule: 2 years

Shelf life after first opening:
The medicinal product should be used immediately after opening the ampoule.

SPECIAL PRECAUTIONS FOR STORAGE
Store in a refrigerator (2 – 8 °C).
Do not freeze.
Keep ampoules in the outer carton in order to protect from light.

NATURE AND CONTENTS OF CONTAINER
2.5 ml, 5 ml and 10 ml in colourless, type I glass ampoules

Pack sizes:
1 Ampoule x 2.5 ml
5 Ampoules x 2.5 ml
10 Ampoules x 2.5 ml
1 Ampoule x 5 ml
5 Ampoules x 5 ml
10 Ampoules x 5 ml
1 Ampoule x 10 ml
5 Ampoules x 10 ml
10 Ampoules x 10 ml

Not all pack sizes may be marketed

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
Any unused product or waste material should be disposed of in accordance with local requirements.

Diluted to concentrations between 0.1 and 2 mg cisatracurium/ml Cisatracurium Kabi is physically and chemically stable for 24 hours at 25 °C in sodium chloride 9 mg/ml (0.9 %) solution; in sodium chloride 9 mg/ml (0.9 %) and glucose 50 mg/ml (5 %) solution; and in glucose 50 mg/ml (5 %) solution.

Cisatracurium has been shown to be compatible with the following commonly used peri-operative medicinal products, when mixed in conditions simulating administration into a running intravenous infusion via a Y-site injection port: alfentanil hydrochloride, droperidol, fentanyl citrate, midazolam hydrochloride and sufentanil citrate. Where other agents are administered through the same indwelling needle or cannula as cisatracurium, it is recommended that each medicinal product be flushed through with an adequate volume of a suitable intravenous fluid, e.g., sodium chloride 9 mg/ml (0.9 %) solution.

MANUFACTURER:
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