TRAKEZE

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
TRAKEZE 10 mg/mL solution for injection/infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 mL of TRAKEZE contains rocuronium bromide 10 mg. Each vial has a total content of rocuronium bromide 50 mg per 5 mL solution.
Sugar free.
Essentially 'sodium free'.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Solution for injection or infusion.
The solution is clear, colourless up to pale brown-yellowish.
pH: 3,5 - 4,5; osmolarity: 270 - 330 mOsmol/kg.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
TRAKEZE is indicated as an adjunct:
- to general anaesthesia to facilitate tracheal intubation during routine and rapid sequence induction, and to provide skeletal muscle relaxation during surgery
- in the intensive care unit (ICU) to facilitate intubation and mechanical ventilation for up to 3 days in adults 18 - 65 years.

4.2 Posology and method of administration
Posology
TRAKEZE should be administered only by experienced medical practitioners familiar with the use of neuromuscular blocking medicines.
The dosage of TRAKEZE should be individualised in each patient. The method of anaesthesia and the expected duration of surgery, the method of sedation and the expected duration of mechanical ventilation, the possible interaction with other medicines that are administered concomitantly, and the condition of the patient should be considered when determining the dose.
The use of an appropriate neuromuscular monitoring technique is recommended for the evaluation of the neuromuscular block and recovery.
Inhalation anaesthetics potentiate the neuromuscular blocking effects of TRAKEZE (see section 4.5). This potentiation becomes clinically relevant during the course of anaesthesia when a certain tissue concentration of the volatile medicines is reached. Consequently, adjustments should be made by administering smaller maintenance doses at less frequent intervals or by using lower infusion rates of TRAKEZE during long lasting procedures (longer than 1 hour) under inhalational anaesthesia (see section 4.5).

Risk of medication errors
Accidental administration of neuromuscular blocking medicines may result in serious adverse events, including fatal outcomes. Store TRAKEZE with the cap and ferrule intact and in a manner that minimises the possibility of selecting the wrong product (see section 4.4).

In adult patients the following dosage recommendations may serve as a general guidance for tracheal intubation and muscle relaxation for short to long lasting surgical procedures and for use in the ICU.

Surgical procedures
Tracheal intubation
The standard intubating dose during routine anaesthesia is rocuronium bromide 0,6 mg per kg body mass, which results in adequate intubation conditions within 90 seconds in nearly all patients.
A dose of TRAKEZE 1,0 mg per kg body mass is recommended for facilitating tracheal intubation conditions during rapid sequence induction of anaesthesia, after which adequate intubation conditions are also established within 60 seconds in nearly all patients.

Higher doses
Should there be a reason for selection of larger doses in individual patients, initial doses up to TRAKEZE 2 mg/kg have been administered during surgery. The use of these high doses of TRAKEZE decreases the onset time and increases the duration of action (see section 5.2).

Maintenance dosing
The recommended maintenance dose is TRAKEZE 0,15 mg per kg body mass. In the case of long-term inhalational anaesthesia, this should be reduced to TRAKEZE 0,075 - 0,1 mg/kg. The maintenance doses should be given as a bolus when twitch height has recovered to 25 % of control twitch height, or when 2 - 3 responses to train-of-four stimulation (TOF) are present (see section 5.2).
No cumulative effect (progressive increase in duration of action) with repetitive maintenance dosing at the recommended level has been observed.

Continuous infusion
If TRAKEZE is administered by continuous infusion, it is recommended to give a loading dose of TRAKEZE 0,6 mg per kg body mass and, when the neuromuscular block starts to recover, to start administration by infusion. The infusion rate should be adjusted to maintain twitch response at 10 % of control twitch height or to maintain 1 - 2 responses to train-of-four stimulation. In adults under intravenous anaesthesia, the infusion rate required to maintain the neuromuscular block at this level ranges from 0,3 - 0,6 mg/kg per hour. Under inhalational anaesthesia the infusion rate ranges from 0,3 - 0,4 mg/kg per hour.
Continuous monitoring of the neuromuscular block is essential since infusion rate requirements vary from patient to patient and with the anaesthetic method used.

Special populations
Elderly patients and patients with hepatic and/or biliary tract disease and/or renal failure
The standard intubation dose for elderly patients and patients with hepatic and/or biliary tract disease and/or renal failure during routine anaesthesia is TRAKEZE 0,6 mg/kg.
Regardless of the anaesthetic technique used, the recommended maintenance dose for these patients is TRAKEZE 0,075 - 0,1 mg/kg and the recommended infusion rate is 0,3 - 0,4 mg/kg per hour (see Continuous infusion).

Dosage in overweight and obese patients
When used in overweight or obese patients (defined as patients with a body weight of 30 % or more above ideal body mass) doses should be reduced considering a lean body mass.

Intensive care procedures
Tracheal intubation
For tracheal intubation, the same doses should be used as described above under surgical procedures.

Maintenance dosing
The use of an initial loading dose of TRAKEZE 0,6 mg per kg body mass is recommended, followed by a continuous infusion as soon as twitch height recovers to 10 % or upon reappearance of 1 - 2 twitches to train-of-four (TOF) stimulation. Dosage should always be titrated to effect in the individual patient. The recommended initial infusion rate for the maintenance of a neuromuscular block of 80 - 90 % (1 - 2 twitches to TOF stimulation) in adult patients is 0,3 - 0,6 mg/kg per hour during the first hour of administration, which will need to be decreased during the following 6 - 12 hours, according to individual response. Thereafter, individual dose requirements remain relatively constant.
A large interpatient variability in hourly infusion rates has been found, with mean hourly infusion rates ranging from 0,2 - 0,5 mg/kg per hour depending on nature and extent of organ failure(s), concomitant medicine and individual patient characteristics. To provide optimal individual patient control, monitoring of neuromuscular transmission is strongly recommended. Safety and efficacy beyond 3 days has not been established.
Following continuous infusion in the ICU, the time to recovery of the TOF ratio to 0,7 depends on the level of block at the end of the infusion. After a continuous infusion for 20 hours or more the median (range) time between return of T2 to TOF stimulation and recovery of the TOF ratio to 0,7 approximates 1,5 (1 - 5) hours in patients without multiple organ failure and 4 (1 - 25) hours in patients with multiple organ failure.

Paediatric population
Dosage in paediatric patients
For infants (28 days - 23 months), children (2 - 14 years) and adolescents (12 - 18 years) the recommended intubation dose during routine anaesthesia and maintenance dose are similar to those in adults.
For continuous infusion in paediatrics the infusion rates, with exception of children, are the same as for adults. For children higher infusion rates might be necessary. For children the same initial infusion rates as for adults are recommended, and this should be adjusted to maintain twitch response at 10 % of control twitch height, or to maintain 1 - 2 responses to train-of-four stimulation during the procedure.
The experience with TRAKEZE in rapid sequence induction in paediatric patients is limited. TRAKEZE is therefore not recommended for facilitating tracheal intubation conditions during rapid sequence induction in paediatric patients.

Method of administration
TRAKEZE is for single use only.
TRAKEZE is administered intravenously either as a bolus injection or as a continuous infusion (see section 6.6 for compatible infusion fluids). Administration should begin immediately after mixing and should be completed within 24 hours. Unused solutions should be discarded.

4.3 Contraindications
TRAKEZE is contraindicated in:
- hypersensitivity to rocuronium bromide, or to the bromide ion, or to any of the ingredients of TRAKEZE (see section 6.1)
- there is inadequate data to support the use of TRAKEZE in neonates (0 - 1 month)
- TRAKEZE is not recommended for the facilitation of mechanical ventilation in the intensive care in paediatric and elderly patients due to a lack of data on safety and efficacy.

4.4 Special warnings and precautions for use

TRAKEZE causes paralysis of the respiratory muscles. Ventilatory support is therefore mandatory for patients treated with TRAKEZE until adequate spontaneous respiration is restored. It is important to anticipate intubation difficulties, particularly when used as part of a rapid sequence induction technique.

Residual neuromuscular blockade
Residual neuromuscular blockade has been reported for rocuronium bromide, as in TRAKEZE (see section 4.8). To prevent complications, it is recommended to extubate only after the patient has recovered sufficiently from neuromuscular block. Other factors which could cause residual neuromuscular blockade after extubation in the post-operative phase (such as medicine interactions or the condition of the patient) should also be considered. If not used as part of standard clinical practice, the use of a reversal medicine should be considered, especially in those cases where residual neuromuscular blockade is more likely to occur.
It is essential to ensure that the patient is breathing spontaneously, deeply and regularly before leaving the theatre after anaesthesia.
Geriatric patients (65 years or older) may be at increased risk for residual neuromuscular block.

Hypersensitivity/anaphylaxis
Severe anaphylactic and anaphylactoid reactions, which may be fatal, can occur after the administration of TRAKEZE (see section 4.8 (c)).
High rates of cross-reactivity between neuromuscular blocking medicines have been reported. Therefore, where possible, before administering TRAKEZE, hypersensitivity to other neuromuscular blocking medicines should be excluded. TRAKEZE should only be used when absolutely essential in susceptible patients. Patients who experience a hypersensitivity reaction under general anaesthesia should be tested subsequently for hypersensitivity to other neuromuscular blockers.

Histamine release and histaminoid reactions
Since neuromuscular blocking substances are known to be capable of inducing histamine release both locally at the site of injection and systemically, the possible occurrence of itching and erythematous reactions at the site of injection and/or generalised histaminoid (anaphylactoid) reactions (see section 4.8), should always be taken into consideration when administering TRAKEZE.

Cardiac effects
TRAKEZE may increase the heart rate (see section 4.8).
Dose levels higher than 0,9 mg per kg body weight may increase the heart rate; this effect could counteract the bradycardia produced by other anaesthetic agents or by vagal stimulation.

Prolonged neuromuscular blockage
Prolonged paralysis and/or skeletal muscle weakness has been noted after long-term use of TRAKEZE in the ICU (see section 4.8).
In order to help preclude possible prolongation of neuromuscular blockage and/or overdose, it is strongly recommended that neuromuscular transmission is monitored throughout the use of TRAKEZE.
Patients should also receive adequate analgesia and sedation. TRAKEZE should furthermore be titrated to effect in the individual patients, or under the supervision of experienced medical practitioners who are familiar with its actions and with appropriate neuromuscular monitoring techniques.

Myopathy
Myopathy has been reported regularly after long-term administration of TRAKEZE in the ICU, in combination with corticosteroids.
In patients receiving both TRAKEZE and corticosteroids, treatment with TRAKEZE should be limited as much as possible.

Suxamethonium
If suxamethonium is used for intubation, the administration of TRAKEZE should be delayed until the patient has clinically recovered from the neuromuscular blockade induced by suxamethonium (see section 4.5).

Malignant hyperthermia
Because TRAKEZE is always used with other medicines and because of the possibility of the occurrence of malignant hyperthermia during anaesthesia, even in the absence of known triggering medicines, medical practitioners should be familiar with the early signs, confirmatory diagnosis and treatment of malignant hyperthermia prior to the start of any anaesthesia. Cases of malignant hyperthermia with rocuronium (as in TRAKEZE) have been reported during post-marketing surveillance; however, a causal association has not been proven.

Risk of death due to medication errors
Administration of TRAKEZE results in paralysis, which may lead to respiratory arrest and death, a progression that may be more likely to occur in a patient for whom it is not intended. Confirm proper selection of intended product and avoid confusion with other injectable solutions that are present in critical care and other clinical settings. If another healthcare provider is administering the product, ensure that the intended dose is clearly labelled and communicated.

The following conditions may influence the pharmacokinetics and/or pharmacodynamics of TRAKEZE:
Hepatic and/or biliary tract disease and renal failure
Rocuronium bromide, as contained in TRAKEZE, is excreted in bile and urine (see section 5.2). Prolongation of action has been reported with doses of TRAKEZE 0,6 mg/kg in patients with clinically significant hepatic and/or biliary disease, or with renal failure/impairment. Therefore, TRAKEZE should be used with caution in these patients.

Prolonged circulation time
Conditions associated with prolonged circulation time such as cardiovascular diseases, old age and oedematous states resulting in an increased volume of distribution, may contribute to a slower onset of the effect. The duration of action may also be prolonged due to reduced plasma clearance.

Neuromuscular disease
TRAKEZE should be used with extreme caution in patients with neuromuscular disease or after poliomyelitis, since the response to neuromuscular blocking medicines may be considerably altered in these cases. The magnitude and direction of this alteration may vary widely. In patients with myasthenia gravis or with the myasthenic (Eaton-Lambert) syndrome, small doses of rocuronium bromide may have profound effects and TRAKEZE should be titrated to the response.

Hypothermia
In surgery under hypothermic conditions, the neuromuscular blocking effect of TRAKEZE is increased and the duration prolonged.

Obesity
TRAKEZE may exhibit a prolonged duration and a prolonged spontaneous recovery in obese patients, when the administered doses are calculated on actual body mass.

Burns
Patients with burns are known to develop resistance to nondepolarising neuromuscular blocking medicines. It is recommended that the dose is titrated to the response.

Conditions which may increase the effects of TRAKEZE
Hypokalaemia (e.g. after severe vomiting, diarrhoea, or diuretic therapy), hypermagnesaemia, hypocalcaemia (after massive transfusions), hypoproteinaemia, dehydration, acidosis, hypercapnia and cachexia.
Severe electrolyte disturbances, altered blood pH or dehydration should therefore be corrected when possible.

Paediatric population
The same warnings and precautions as for adults should be taken into consideration.

Information on excipients of TRAKEZE
TRAKEZE contains sodium. TRAKEZE contains less than 1 mmol (0,023 g) sodium per 1 mL, that is to say essentially 'sodium free'.

4.5 Interaction with other medicines and other forms of interaction
The following medicines have been shown to influence the extent and/or duration of the effect of TRAKEZE:
Increased effect
- halogenated volatile anaesthetics potentiate the neuromuscular block of TRAKEZE. The effect only becomes apparent with maintenance dosing (see section 4.2 – Surgical procedures, Maintenance dosing). Reversal of the block with acetylcholinesterase inhibitors could also be inhibited
- after intubation with suxamethonium (see section 4.2 and 4.8)
- long-term concomitant use of corticosteroids and TRAKEZE in the ICU may result in prolonged duration of neuromuscular block or myopathy (see section 4.4 and 4.8)
- high doses of thiopental, methohexital, ketamine, fentanyl, gamma-hydroxybutyrate, etomidate and propofol
- other nondepolarising neuromuscular blocking agents.

Other medicines:
- antibiotics: aminoglycosides, lincosamides (e.g. lincomycin and clindamycin), polypeptide antibiotics, acylamino-penicillin antibiotics, tetracyclines, high doses of metronidazole
- diuretics, thiamine, monoamine oxidase (MAO) inhibiting agents, quinidine, quinine, protamine, adrenergic blocking agents, magnesium salts, calcium channel blocking medicines, lithium salts, local anaesthetics (lidocaine IV, bupivacaine epidural) and acute administration of phenytoin of ß-blocking medicines.

Recurarisation (increase in neuromuscular block after a variable period of recovery) has been reported after post-operative administration of aminoglycoside, lincosamide, polypeptide and acylaminopenicillin antibiotics, quinidine, quinine and magnesium salts (see section 4.4).

Decreased effect
- prior chronic administration of corticosteroids, phenytoin or carbamazepine
- calcium chloride, potassium chloride, noradrenaline, azathioprine (only transient and limited effect), theophylline
- protease inhibitor homologues (such as gabexate and ulinastatin)
- neostigmine, edrophonium, pyridostigmine, aminopyridine derivatives.

Variable effect
Administration of other nondepolarising neuromuscular blocking medicines in combination with TRAKEZE may produce attenuation of potentiation of the neuromuscular block, depending on the order of administration and the neuromuscular blocking medicines used.
Suxamethonium given after the administration of TRAKEZE may produce potentiation or attenuation of the neuromuscular blocking effect of TRAKEZE.

Effect of TRAKEZE on other medicines
Combined use of TRAKEZE with lidocaine could result in a quicker onset of action of lidocaine.

Paediatric population
No formal interaction studies have been reported.

4.6 Fertility, pregnancy and lactation
Pregnancy
The safety of use of TRAKEZE in pregnancy has not been established.

Caesarean section
In patients undergoing a caesarean section, TRAKEZE can be used as part of a rapid sequence induction technique, provided no intubation difficulties are anticipated and a sufficient dose of anaesthetic medicine is administered or following suxamethonium facilitated intubation.
However, TRAKEZE, administered in doses of 0,6 mg/kg may not produce adequate conditions for intubation until 90 seconds after administration. This dose has been shown to be safe in patients undergoing a caesarean section. TRAKEZE does not affect Apgar score, foetal muscle tone or cardiorespiratory adaptation.
From umbilical cord blood sampling it is apparent that only limited placental transfer of rocuronium bromide occurs which does not lead to the observation of clinical adverse effects in the newborn. Doses of 1,0 mg/kg have not been investigated in caesarean section patients. Therefore, only a dose of 0,6 mg/kg is recommended in this patient group.
Reversal of neuromuscular block induced by neuromuscular blocking medicines may be inhibited or unsatisfactory in patients receiving magnesium salts for toxaemia of pregnancy, because magnesium salts enhance neuromuscular blockade. Therefore, in these patients the dosage of TRAKEZE should be reduced and be titrated to twitch response.

Breastfeeding
The safety of use of TRAKEZE in lactation has not yet been established.

Fertility
There is no data on fertility with TRAKEZE.

4.7 Effects on ability to drive and use machines
TRAKEZE has a major influence on the ability to drive and use machines.
Patients should be warned not to handle potentially dangerous machinery or drive a car within 24 hours after the full recovery from the neuromuscular blocking action of TRAKEZE.

4.8 Undesirable effects
a. Summary of the safety profile
The most common undesirable effects are pain/reaction around injection site, changes in vital functions and prolonged neuromuscular block. The most frequently reported serious adverse medicine reactions during post-marketing surveillance is anaphylactic and anaphylactoid reactions and associated symptoms.

b. Tabulated list of adverse reactions

System Organ Class	Frequency	Side effects
Immune system disorders	*Less frequent*	Hypersensitivity, anaphylactic reaction (sometimes fatal), anaphylactic shock, anaphylactoid reaction (see section 4.4), angioedema
Nervous system disorders	*Less frequent* *Frequency unknown*	Flaccid paralysis Kounis syndrome
Cardiac disorders	*Less frequent*	Tachycardia
Vascular disorders	*Less frequent*	Hypotension, circulatory collapse and shock, flushing
Respiratory, thoracic and mediastinal disorders	*Less frequent* *Frequency unknown*	Bronchospasm Apnoea, respiratory failure
Skin and subcutaneous tissue disorders	*Less frequent*	Urticaria, rash, erythematous rash, itching, angioneurotic oedema
Musculoskeletal, connective tissue and bone disorders	*Less frequent*	Muscular weakness, steroid myopathy (see section 4.4)
General disorders and administrative site conditions	*Less frequent* *Frequency unknown*	Medicine ineffective, decreased medicine effect/therapeutic response, increased medicine effect/therapeutic response, injection site pain, injection site reaction, facial oedema Malignant hyperthermia
Investigations	*Less frequent*	Prolonged neuromuscular block (see section 4.4), delayed recovery from anaesthesia, airway complication of anaesthesia

c. Description of selected adverse reactions
Anaphylaxis
Severe anaphylactic reactions to neuromuscular blocking medicines, including TRAKEZE, have been reported (see section 4.8). Anaphylactic/anaphylactoid reactions are bronchospasm, cardiovascular changes (e.g. hypotension, tachycardia, circulatory collapse – shock), and cutaneous changes (e.g. angioedema, urticaria). These reactions have, in some cases, been fatal.
Due to the possible severity of these reactions, one should always assume they may occur and take the necessary precautions.
Clinical study reports mention a slight increase in mean plasma histamine level following rapid bolus administration of rocuronium bromide 0,3 - 0,9 mg per kg body weight.

Prolonged neuromuscular block
The most frequent adverse reaction to nondepolarising blocking medicines as a class consists of an extension of the medicine's pharmacological action beyond the time period needed. This may vary from skeletal muscle weakness to profound and prolonged skeletal muscle paralysis resulting in respiratory insufficiency or apnoea (see section 4.4).

Myopathy
Myopathy has been reported after the use of various neuromuscular blocking medicines in the ICU in combination with corticosteroids (see section 4.4).

Local injection site reactions
During rapid sequence induction of anaesthesia, pain on injection has been reported, especially when the patient has not yet completely lost consciousness and particularly when propofol is used for induction. Clinical study reports mention pain on injection in 16 % of the patients who underwent rapid sequence induction of anaesthesia with propofol and in less than 0,5 % of the patients who underwent rapid sequence induction of anaesthesia with fentanyl and thiopental.

d. Paediatric population
A meta-analysis of 11 clinical studies in paediatric patients (n=704) with rocuronium bromide (up to 1 mg/kg) showed that tachycardia was identified as an adverse medicine reaction with a frequency of 1,4 %.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Signs and symptoms:
In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Management of overdose:
In the event of overdose and prolonged neuromuscular block, the patient should continue to receive ventilatory support and sedation. Upon start of spontaneous recovery, sugammadex or an acetylcholinesterase inhibitor (e.g. neostigmine, edrophonium, pyridostigmine) should be administered in adequate doses. When administration of an acetylcholinesterase inhibiting medicine fails to reverse the neuromuscular effects of TRAKEZE, artificial ventilation must be continued until spontaneous breathing is restored. Repeated dosages of an acetylcholinesterase inhibitor can be dangerous.
Further treatment is symptomatic and supportive.
In animal studies, severe depression of cardiovascular function, ultimately leading to cardiac collapse did not occur until a cumulative dose of 750 x ED_{90} 135 mg/kg was administered.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: muscle relaxants, peripherally acting agents, other quaternary ammonium compounds.
ATC code: M03AC09.
Pharmacological classification: A 17.1 Peripherally acting muscle relaxants.

Mechanism of action
Rocuronium bromide is a nondepolarising neuromuscular blocking medicine. It acts by competing for nicotinic ACh (acetylcholine) receptors at the motor endplate. The latter action is antagonised by acetylcholinesterase inhibitors such as neostigmine, edrophonium and pyridostigmine.
The ED_{90} (dose required to produce 90 % depression of the twitch response of the thumb to stimulation of the ulnar nerve) during intravenous anaesthesia is approximately rocuronium bromide 0,3 mg/kg. The ED_{90} in infants is lower than in adults and children (0,25; 0,35 and 0,40 mg/kg, respectively).
The clinical duration (the duration until spontaneous recovery to 25 % of control twitch height) with rocuronium bromide 0,6 mg/kg is 30 - 40 minutes. The total duration (time until spontaneous recovery to 90 % of control twitch height) is 50 minutes. The mean time of spontaneous recovery of twitch response from 25 - 75 % (recovery index) after a bolus dose of rocuronium bromide 0,6 mg/kg is 14 minutes.
With lower dosages of rocuronium bromide 0,3 - 0,45 mg/kg (1 - 1,5 x ED_{90}), onset of action is slower, and duration of action is shorter. With high doses of 2 mg/kg, clinical duration is 110 minutes.

Cardiovascular surgery
In patients scheduled for cardiovascular surgery the most common cardiovascular changes during the onset of maximum block following rocuronium bromide 0,6 - 0,9 mg/kg are an increase in heart rate up to 9 % and an increase in mean arterial blood pressure up to 16 % from the control values.

Reversal of muscle relaxation
Administration of acetylcholinesterase inhibitors, (neostigmine, pyridostigmine or edrophonium) at reappearance of T2 or at the first signs of clinical recovery, antagonises the action of rocuronium bromide.

Paediatric population
The mean onset time in infants and children at an intubation dose of 0,6 mg/kg is slightly shorter than in adults. The duration of relaxation and the time to recovery tend to be shorter in children compared to infants and adults.

5.2 Pharmacokinetic properties
Absorption and distribution:
After intravenous administration of a single bolus dose, the plasma concentration time course runs in three exponential phases. In normal adults, the mean (95 % CI) elimination half-life is 73 (66 - 80) minutes, the (apparent) volume of distribution at steady state conditions is 203 (193 - 214) mL/kg and the plasma clearance is 3,7 (3,5 - 3,9) mL/kg per minute.

When administered as a continuous infusion to facilitate mechanical ventilation for 20 hours or more, the mean elimination half-life and the mean (apparent) volume of distribution at steady state are increased. A large variability amongst patients exists, related to nature and extent of (multiple) organ failure and individual patient characteristics. In patients with multiple organ failure the mean (± SD) elimination half-life is 21,5 (± 3,3) hours, the (apparent) volume of distribution at steady state is 1,5 (± 0,8) L/kg and the plasma clearance rate is 2,1 (± 0,8) mL/kg per minute.

Elimination:
Rocuronium is excreted in urine and bile. Excretion in urine is nearly 40 % within 12 - 24 hours. After injection of a radio-labelled dose of rocuronium bromide, excretion of the radiolabel is on average 47 % in urine and 43 % in faeces after 9 days. About 50 % is recovered as the parent compound.

Pharmacokinetics in special patient groups
Elderly patients and patients with renal or hepatic disease
The plasma clearance in elderly patients and in patients with renal dysfunction is reduced but does not reach the level of statistical significance. In patients with hepatic disease, the mean elimination half-life is prolonged by 30 minutes and the mean plasma clearance is reduced by 1 mL/kg per minute.

Paediatric population
In infants (3 months - 1 year), the apparent volume of distribution at steady state conditions is increased compared to adults and children (1 - 8 years). In older children (3 - 8 years), a trend is seen towards higher clearance and shorter elimination half-life (approximately 20 minutes) compared to adults, younger children and infants.

5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
TRAKEZE contains the following excipients:
Acetic acid 99 % (for pH adjustment)
Acetic acid 30 % (for pH adjustment)
Sodium acetate trihydrate
Sodium chloride
Sodium hydroxide (for pH adjustment)
Water for injections.
No preservatives have been added.

6.2 Incompatibilities
Physical incompatibility has been documented for TRAKEZE when added to solutions containing the following active substances: amphotericin, amoxicillin, azathioprine, cefazolin, cloxacillin, dexamethasone, diazepam, enoximone, erythromycin, famotidine, furosemide, hydrocortisone sodium succinate, insulin, intralipid, methohexital, methylprednisolone, prednisolone sodium succinate, thiopental, trimethoprim, and vancomycin.
TRAKEZE must not be mixed with other medicines except those mentioned in section 6.6.
If TRAKEZE is administered via the same infusion line that is also used for other medicines, it is important that this infusion line is adequately flushed (e.g. with 0,9 % NaCl) between administration of TRAKEZE and other medicines.

6.3 Shelf life
TRAKEZE has a shelf life of 3 years, if stored as described in section 6.4.
Since TRAKEZE does not contain a preservative, the solution should be used immediately after opening the vial.
From a microbiological point of view, the diluted product should therefore be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 - 8 ºC, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage
Store in a refrigerator (2 - 8 ºC). Do not freeze. Protect from light.

If stored out of a refrigerator:
TRAKEZE may be stored outside the refrigerator at a temperature of up to 25 °C for a maximum of 12 weeks. The storage period must not exceed the shelf life.

Storage conditions after opening of the vial:
See section 6.3.

6.5 Nature and contents of container
TRAKEZE is packaged in a clear Type I 10 mL glass vial containing 5 mL solution, with a vial neck of 20 mm, closed with a bromobutyl rubber stopper and a polypropylene flip-off cap.
Folding boxes contain 10 vials each.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
TRAKEZE is compatible with water for injection, 0,9 % sodium chloride, 5 % glucose, sodium chloride 0,3 % and glucose 3,3 %, sodium chloride 0,45 % in glucose 2,5 % and lactated Ringer's solution.
Administration should begin immediately after mixing and should be completed within 24 hours.
Do not use TRAKEZE if you notice that the solution is not clear and not free from particles.
For single use only. Unused solutions should be discarded.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa

8. REGISTRATION NUMBER
A53/17.1/0159.158

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15 June 2020

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15 April 2024

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

TRAKEZE 10 mg/mL solution for injection/infusion
Rocuronium bromide
Sugar free
Essentially 'sodium free'

Read all of this leaflet carefully before you are given TRAKEZE
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What TRAKEZE is and what it is used for
2. What you need to know before you are given TRAKEZE
3. How TRAKEZE will be administered
4. Possible side effects
5. How TRAKEZE will be stored
6. Contents of the pack and other information

1. What TRAKEZE is and what it is used for
TRAKEZE contains rocuronium bromide, one of a group of medicines called muscle relaxants.

TRAKEZE acts by blocking the impulses from the nerves to the muscles, thereby causing the muscles to relax.
When you have an operation, your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation. TRAKEZE may be used if you are receiving anaesthesia to ease the insertion of a tube into your trachea (windpipe) for artificial ventilation (mechanical assistance of breathing). TRAKEZE may also be used as an adjunct in the intensive care unit (ICU) (e.g. to ease the insertion of a tube into your windpipe), for short term use.

TRAKEZE may be given to paediatric patients aged 28 days - 18 years (term infants to adolescents), as an adjunct to general anaesthesia to ease the insertion of a tube into the trachea (windpipe) of your child for artificial ventilation (mechanical assistance of breathing) and to relax the muscles.

2. What you need to know before you are given TRAKEZE
TRAKEZE should not be administered to you:
Tell your doctor or healthcare professional before being given the injection:
- if you are hypersensitive (allergic) to rocuronium bromide or the bromide ion, or any of the other ingredients of TRAKEZE (see section 6).

TRAKEZE is contraindicated in newborn babies (up to 1 month old) and is not recommended in the facilitation of mechanical ventilation in the intensive care in children and elderly patients (older than 65 years).

Warnings and precautions
Tell your doctor or healthcare professional before being given the injection:
Special care should be taken with TRAKEZE:
- if you are allergic to any muscle relaxant
- if your liver does not work well or you have a biliary disease
- if your kidneys do not work well
- if you have a heart disease or a disease affecting your blood circulation
- if you take or used corticosteroids (medicines for inflammation). Myopathy (a disease of muscle tissue) may occur if these medicines are used together with TRAKEZE
- if you have a disease affecting the nerves and muscles (neuromuscular diseases, e.g. polio, myasthenia gravis or Eaton-Lambert syndrome)
- if you have burnt your skin
- if you have a low potassium level in the blood (hypokalaemia). Some causes may be severe vomiting, diarrhoea or diuretic therapy
- if you have a low calcium level in the blood (hypocalcaemia)
- if you have a high magnesium level in the blood (hypermagnesaemia)
- if you have low levels of proteins in the blood (hypoproteinaemia)
- if you suffer from dehydration (you use or lose more fluid than you take in)
- if you have an increased amount of acids in the blood (acidosis)
- if you have an increased amount of carbon dioxide in the blood (hypercapnia)
- if you suffer from excessive loss of weight (cachexia)
- if you have ever developed a very low body temperature (hypothermia).

If you are suffering from any of the above conditions your anaesthetist will take this into account when deciding on the correct dose of TRAKEZE for you.

Prolonged paralysis and/or muscle weakness may occur in some patients (see Possible side effects). You will be carefully observed in hospital, during and after the operation.

Children
There is inadequate data to support the use of TRAKEZE in neonates (0 - 1 month).

Other medicines and TRAKEZE
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Please tell your doctor or pharmacist if you are taking, or have recently taken or used:
Medicines which increase the effect of TRAKEZE:
- corticosteroids (such as dexamethasone in the long-term use for asthma or inflammation)
- antibiotics (such as lincomycin, clindamycin, tetracyclines, high doses of metronidazole and penicillins)
- lithium (may be used for certain psychiatric disorders)
- local anaesthetics (such as lidocaine or bupivacaine)
- medicines used for the treatment of a heart disease (such as quinidine) or high blood pressure (such as calcium channel blocking medicines or beta blockers)
- diuretics or "water pills" (medicines which increase the amount of urine)
- magnesium salts (laxatives or diet supplements)
- quinine (used for malaria).

Medicines which decrease the effect of TRAKEZE:
- medicines used for epilepsy treatment (such as phenytoin, carbamazepine)
- potassium chloride
- calcium chloride
- noradrenaline (to increase and maintain blood pressure in limited, short-term serious health situations)
- azathioprine (controls rheumatoid arthritis)
- theophylline (to treat asthma and chronic obstructive pulmonary disease)
- protease inhibitors, such as gabexate and ulinastatin (medicines used for the treatment or prevention of a viral infection)
- neostigmine or pyridostigmine (medicines used for the treatment of myasthenia gravis).

You may be given other medicines during the procedure which can influence the effects of TRAKEZE. These may include certain anaesthetics (such as local anaesthetics, general or inhalational anaesthetics) or other muscle relaxants (such as suxamethonium). Your doctor will take this into account when deciding on a suitable dose of TRAKEZE for you.

TRAKEZE may make certain anaesthetics work more quickly. Your anaesthetist will take this into account when deciding the correct dose of TRAKEZE.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before TRAKEZE is administered to you.
TRAKEZE should not be given to pregnant or nursing women, as safety of its use in pregnancy and breastfeeding has not been established.
TRAKEZE may be given during caesarean section.
There is no data on fertility with TRAKEZE.

Driving and using machines
TRAKEZE can significantly affect your ability to drive a vehicle or to use machines (see Possible side effects). Do not drive a vehicle or use potentially dangerous machines during the first 24 hours.
Ask a responsible adult to take you home after your treatment. Ask your doctor when you can start driving and using machines again.
It is not always possible to predict to what extent TRAKEZE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TRAKEZE affects them.

TRAKEZE contains sodium
TRAKEZE contains less than 1 mmol (0,023 g) sodium per 1 mL, that is to say essentially 'sodium free'.

3. How TRAKEZE will be administered
You will not be expected to give yourself TRAKEZE. It will be given to you by a person who is qualified to do so (an anaesthetist).
TRAKEZE is given to you intravenously, either as a single injection or as a continuous infusion (over a longer period) into a vein.

Adults:
The usual dose is 0,6 mg per kg body weight and its effect will last 30 - 40 minutes. Your anaesthetist will ensure that you receive the correct dose. It depends on many factors, such as medicine interactions (their cross activity), the estimated length of surgery as well as your age and clinical condition. During the surgery the effect of TRAKEZE is controlled continuously.

Use in children and adolescents (0 - < 18 years of age):
TRAKEZE may be given to infants (28 days - 23 months), children (2 - 14 years) and adolescents (12 - 18 years). There is inadequate data to support the use of TRAKEZE in neonates (0 - 1 month).

The dose and its effect in children are similar to those in adults, but the anaesthetist will adjust the dose according to the needs of your child. Your doctor will consider if higher infusion rates might be necessary.
Your doctor will tell you how long your treatment with TRAKEZE will last.
If you have the impression that the effect of TRAKEZE is too strong or too weak, tell your doctor or pharmacist.

If you receive more TRAKEZE than you should
Since a healthcare professional will administer TRAKEZE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdose. Your anaesthetist will carefully monitor your pulse rate, temperature, rate of breathing and blood pressure while you are treated with TRAKEZE, therefore it is unlikely that you will be given too much TRAKEZE.

4. Possible side effects
TRAKEZE can have side effects.
Not all side effects reported for TRAKEZE are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using TRAKEZE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- welts, urticaria (hives), red skin, widespread severe rash and itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRAKEZE. You may need urgent medical attention or hospitalisation.

Less frequent side effects:
- loss of movement (paralysis)
- quicker than usual heartbeat (tachycardia)
- increased level of histamine in the blood
- lowering of blood pressure (hypotension)
- failure of circulation (circulatory collapse and shock)
- flushing
- wheezing (bronchospasm)
- itching, rash or redness of the skin, swelling
- muscle weakness, which may be worse if you have been treated with corticosteroids (see Other medicines and TRAKEZE)
- prolonged effect of muscle relaxation (prolonged neuromuscular block)
- pain and redness at the injection site.

The following side effects have been reported but the frequency for them to occur is not known:
- Kounis syndrome which is a sudden allergic reaction which can cause chest pain and blocking of the arteries
- breathing (respiratory) failure, temporary cessation of breathing (apnoea)
- sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles (malignant hyperthermia).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.
By reporting side effects, you can help provide more information on the safety of TRAKEZE. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How TRAKEZE will be stored
Store all medicines out of reach of children.
TRAKEZE is stored in a refrigerator (2 - 8 ºC) in the hospital and protected from light. Do not freeze.
TRAKEZE may be stored outside the refrigerator at a temperature of up to 25 °C for a maximum of 12 weeks. The storage period must not exceed the shelf life.

After dilution:
From a microbiological point of view, the diluted product should therefore be used immediately after opening the vial. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 - 8 ºC, unless dilution has taken place in controlled and validated aseptic conditions.
Any unused solutions should be discarded.
Do not use TRAKEZE if you notice the solution is not clear or free from particles.
Do not use after the expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What TRAKEZE contains:
The active substance is rocuronium bromide.
1 mL contains rocuronium bromide 10 mg.
Each vial has a total content of rocuronium bromide 50 mg per 5 mL solution.

The other ingredients are acetic acid (for pH adjustment), sodium acetate trihydrate, sodium chloride, sodium hydroxide (for pH adjustment) and water for injections.

What TRAKEZE looks like and contents of the pack
TRAKEZE is a clear, colourless up to pale brown-yellowish solution.

Pack size:
The product is packaged in a clear Type I 10 mL glass vial containing 5 mL solution, with a vial neck of 20 mm, closed with a bromobutyl rubber stopper and a polypropylene flip-off cap.
Folding boxes contain 10 vials each.
Not all packing sizes may be marketed.

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

TRAKEZE 10 mg/mL oplossing vir inspuiting/infusie
Rokuroniumbromied
Suikervry
Wesenlik 'natriumvry'

Lees die hele inligtingsblad sorgvuldig deur voordat TRAKEZE aan u toegedien word
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u nog vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.

Inhoud van hierdie inligtingsblad

1. Wat TRAKEZE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u TRAKEZE gegee word
3. Hoe TRAKEZE toegedien sal word
4. Moontlike newe-effekte
5. Hoe TRAKEZE bewaar sal word
6. Verpakkingsinhoud en ander inligting

1. Wat TRAKEZE is en waarvoor dit gebruik word
Rokuroniumbromied behoort aan 'n groep medisyne wat bekend staan as spierverslappers.

TRAKEZE werk deur die senu-impulse na die spiere te blokkeer, en sodoende die spiere laat verslap.
Wanneer u 'n operasie ondergaan moet u spiere heeltemal verslap wees. Dit maak dit makliker vir die chirurg om die operasie uit te voer. TRAKEZE kan ook gebruik word indien u narkose ontvang, om die buis makliker in u tragea (lugpyp) te plaas vir kunsmatige asemhaling (meganiese asemhalingsbystand). TRAKEZE kan ook oor 'n kort tydperk gebruik word as 'n aanvullende behandeling in die intensiewe sorgeenheid (ICU) (bv. om dit makliker te maak om 'n buis in u lugpyp te plaas).

TRAKEZE mag aan pediatriese pasiënte van 28 dae tot 18 jaar oud (babas tot adolessente), aanvullend tot algemene narkose toegedien word, om inplasing van 'n buis in die lugpyp van u kind vir kunsmatige ventilasie (meganiese bystand met asemhaling) te vergemaklik en om die spiere te ontspan.

2. Wat u moet weet voordat u TRAKEZE gegee word
TRAKEZE moet nie aan u toegedien word:
Vertel u dokter of gesondheidsorgverskaffer, voordat die inspuiting aan u toegedien word, indien:
- u hipersensitief (allergies) is vir rokuroniumbromied of die bromied-ioon, of vir enige van die ander bestanddele van TRAKEZE (gelys in afdeling 6).

TRAKEZE word teenaangedui by pasgebore babas (tot en met 1 maand oud) en word nie aanbeveel met die fasilitering van meganiese ventilasie in die intensiewe sorg by kinders en bejaarde pasiënte (ouer as 65 jaar), nie.

Waarskuwings en voorsorgmaatreëls
Lig u dokter of gesondheidsorgverskaffer van die volgende in, voordat die inspuiting aan u toegedien word:
Spesiale sorg moet geneem word met TRAKEZE:
- indien u allergies is vir enige spierverslapper
- indien u lewer nie goed werk nie of u 'n galsiekte het
- indien u niere nie goed funksioneer nie
- indien u 'n hartsiekte het, of 'n siekte wat u bloedsomloop aantas
- indien u tans of voorheen kortikosteroïede (medisyne vir inflammasie) neem, of geneem het nie. Miopatie ('n siekte van die spierweefsel) mag voorkom indien hierdie medisyne saam met TRAKEZE geneem word
- indien u 'n siekte het wat die senuwees en spiere aantas (neuromuskulêre siektes, bv. polio, miastenie gravis of Eaton-Lambert se sindroom)
- indien u u vel gebrand het
- indien u 'n lae kaliumvlak in die bloed het (hipokalemie). Sommige oorsake kan erge braking, diarree of diuretiese behandeling wees
- indien u 'n lae kalsiumvlak in die bloed het (hipokalsemie)
- indien u 'n hoë magnesiumvlak in die bloed het (hipermagnesemie)
- indien u lae proteïenvlakke in die bloed het (hipoproteïenemie)
- indien u aan ontwatering ly (u gebruik of verloor meer vloeistof as wat u inneem)
- indien u verhoogde hoeveelhede sure in die bloed het (asidose)
- indien u 'n verhoogde koolsuurgasvlak in die bloed het (hiperkapnie)
- indien u aan buitensporige gewigsverlies (kageksie) ly
- indien u al voorheen 'n baie lae liggaamstemperatuur ontwikkel het (hipotermie).

Indien u aan enige van die bogenoemde toestande ly, sal u narkotiseur dit in ag neem, wanneer daar besluit word op die gepaste TRAKEZE dosering vir u.

Langdurige verlamming en/of spierswakheid mag by sommige pasiënte voorkom (sien Moontlike newe-effekte). Daar sal noukeurig toesig oor u gehou word in die hospitaal, tydens en na die operasie.

Kinders
Daar is onvoldoende data om die gebruik van TRAKEZE vir pasgeborenes (0 - 1 maand), te ondersteun.

Ander medisyne en TRAKEZE
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit aanvullende, of tradisionele medisyne in).

Vertel asseblief u dokter of apteker indien u tans of onlangs die volgende neem, of geneem het:
Medisyne wat die werking van TRAKEZE versterk:
- kortikosteroïede (soos deksametasoon, vir langtermyngebruik met asma of inflammasie)
- antibiotika (soos linkomisien, klindamisien tertrasikliene, hoë dosisse metronidasool en penisilliene)
- litium (mag vir sekere psigiatriese versteurings gebruik word)
- lokale verdowingsmiddels (soos lidokaïen of bupivakaïen)
- medisyne wat gebruik word vir die behandeling van hartsiekte (soos kinidien) of hoë bloeddruk (soos kalsiumkanaalblokkers of betablokkers)
- diuretika of "waterpille" (medisyne wat die volume uriene verhoog)
- magnesiumsoute (lakseermiddels of dieetaanvullings)
- kinien (gebruik vir malaria).

Medisyne wat die werking van TRAKEZE verswak:
- medisyne wat vir epilepsie behandeling gebruik word (soos fenitoïen, karbamasepien)
- kaliumchloried
- kalsiumchloried
- noradrenalien (om bloeddruk te verhoog en te beheer tydens beperkte, korttermyn, ernstige, gesondheidstoestande)
- asatioprien (beheer rumatoïede artritis)
- teofillien (om asma en chroniese obstruktiewe pulmonêre siekte te behandel)
- proteaseremmers, soos gabeksaat en ulinastatien (medisyne wat gebruik word vir die behandeling of voorkoming van 'n virusinfeksie)
- neostigmien of piridostigmien (medisyne gebruik vir die behandeling van miastenie gravis).

Tydens die prosedure mag daar ander medisynes, wat die werking van TRAKEZE kan beïnvloed, aan u toegedien word. Dit kan sekere narkosemiddels (soos lokale verdowingsmiddels, algemene- of inhalasienarkosemiddels) of ander spierverslappers, insluit. U dokter sal dit in ag neem wanneer daar oor 'n gepaste dosis TRAKEZE, vir u besluit word.

TRAKEZE mag veroorsaak dat sekere narkosemiddels vinniger werk. U narkotiseur sal dit in ag neem, wanneer daar op die gepaste dosis vir u besluit word.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat TRAKEZE aan u toegedien word.
TRAKEZE moet nie aan swanger vrouens of die wie borsvoed toegedien word nie, aangesien veiligheid van gebruik tydens swangerskap en borsvoeding nie vasgestel is nie.
TRAKEZE mag tydens 'n keisersnit toegedien word.
Daar is geen data aangaande fertiliteit en die gebruik van TRAKEZE nie.

Bestuur en die hantering van masjiene
TRAKEZE kan u vermoë om te bestuur of masjiene te hanteer aansienlik aantas (sien Moontlike newe-effekte). Moenie 'n voertuig bestuur of moontlik gevaarlike masjinerie tydens die eerste 24 uur gebruik nie.
Vra 'n verantwoordelike volwassene om u na u behandeling huis toe te neem. Vra u dokter wanneer u weer kan begin bestuur en masjinerie gebruik.
Dit is nie altyd moontlik om te voorspel tot watter mate TRAKEZE met die daaglikse aktiwiteite van 'n pasiënt sal inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is hoe TRAKEZE hulle aantas nie.

TRAKEZE bevat natrium
TRAKEZE bevat minder as 1 mmol (0,023 g) natrium per 1 mL, dit wil sê wesenlik 'natriumvry'.

3. Hoe TRAKEZE toegedien sal word
Daar sal nie van u verwag word om TRAKEZE aan uself toe te dien nie. Dit sal aan u toegedien word deur 'n persoon wie bevoeg is om dit te doen ('n narkotiseur).
TRAKEZE word binneaars aan u toegedien, deur 'n enkele inspuiting of as 'n aaneenlopende infusie (oor 'n langer tydperk), in 'n aar.

Volwassenes:
Die gewone dosis is 0,6 mg per kg liggaamsgewig en die effek daarvan sal vir 30 - 40 minute duur. U narkotiseur sal verseker dat u die gepaste dosis ontvang. Dit hang van baie faktore af, soos medisyne-interaksies (die wisselwerking), die geskatte duur van die operasie en ook u ouderdom en kliniese toestand. Tydens die operasie word die effek van TRAKEZE deurlopend beheer.

Gebruik deur kinders en adolessente (0 - < 18 jaar oud):
TRAKEZE mag aan babas (28 dae - 23 maande), kinders (2 - 14 jaar oud) en adolessente (12 - 18 jaar oud) toegedien word. Daar is onvoldoende data om die gebruik van TRAKEZE aan pasgeborenes (0 - 1 maand), te ondersteun.

Die dosis en die effek daarvan op kinders is soortgelyk aan dié by volwassenes, maar die narkotiseur sal die dosis volgens u kind se behoeftes aanpas. U dokter sal oorweeg of 'n hoër infusietempo benodig word.
U dokter sal aandui hoe lank u behandeling met TRAKEZE sal voortduur. Indien u die indruk kry dat die effek van TRAKEZE té sterk of té swak is, raadpleeg u dokter of apteker.

Indien u meer TRAKEZE ontvang as wat u behoort
Aangesien 'n gesondheidsorgdeskundige TRAKEZE sal toedien, sal hy/sy die dosis beheer. In 'n geval van oordosering sal u dokter egter die oordosering behandel.
U narkotiseur sal u polsslag, temperatuur, asemhalingstempo en bloeddruk noukeurig moniteer terwyl u met TRAKEZE behandel word en daarom is dit onwaarskynlik dat daar te veel TRAKEZE aan u toegedien sal word.

4. Moontlike newe-effekte
TRAKEZE kan newe-effekte hê.
Nie alle newe-effekte wat vir TRAKEZE aangemeld is, word by hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of u enige ongunstige effekte ervaar terwyl u TRAKEZE ontvang, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgdeskundige vir advies.

Indien enige van die volgende gebeur, vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of asemhaling mag bemoeilik
- galbulte, urtikarie (netelroos), rooi vel, wydverspreide erge uitslag en gejeuk.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ondervind, kon u moontlik 'n ernstige allergiese reaksie teenoor TRAKEZE ervaar het. U mag dringende mediese aandag of hospitalisasie benodig.

Minder algemene newe-effekte:
- bewegingsverlies (verlamming)
- hartklop kom vinniger as gewoonlik voor (tagikardie)
- verhoogde histamienvlak in die bloed
- verlaagde bloeddruk (hipotensie)
- bloedsomloop faal (sirkulatoriese ineenstorting en skok)
- gloede
- hyging (brongospasma)
- jeuk, uitslag of rooiheid van die vel, swelling
- spierswakheid, wat erger mag word indien u met kortikosteroïede behandel is (sien Ander medisynes en TRAKEZE)
- langdurige effek van spierverslapping (verlengde neuromuskulêre blok)
- pyn en rooiheid by die inspuitingsplek.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms is onbekend:
- Kounis-sindroom, wat 'n skielike allergiese reaksie is en borspyn en die blokkasie van die arteries mag veroorsaak
- asemhalings- (respiratoriese) ineenstorting, tydelike onderbreking van asemhaling (apnee)
- skielike koors, met vinnige hartklop, vinnige asemhaling en styfheid, pyn en/of swakheid in u spiere (maligne hipertermie).

Indien u enige newe-effekte opmerk wat nie in hierdie inligtingsblad vermeld word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van TRAKEZE in te win. U kan ook 'n epos direk aan die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die produk te verseker.

5. Hoe TRAKEZE bewaar sal word
Bewaar alle medisyne buite die bereik van kinders.
TRAKEZE word in 'n yskas (2 - 8 °C) in die hospitaal bewaar en teen lig beskerm.
Moenie vries nie.
TRAKEZE mag hoogstens 12 weke buite die yskas teen 'n temperatuur van tot en met 25 °C geberg word. Die bergingstyd moet nie die rakleeftyd oorskry nie.

Na verdunning:
Vanuit 'n mikrobiologiese oogpunt moet die verdunde produk dadelik gebruik word nadat die flessie oopgemaak is. Indien dit nie dadelik gebruik word nie, is die bergingstye tydens gebruik asook die toestande voor gebruik die verantwoordelikheid van die gebruiker en sou dit normaalweg nie langer as 24 uur teen 2 - 8 °C wees nie, tensy verdunning onder gekontroleerde en gevalideerde aseptiese toestande plaasgevind het.
Alle ongebruikte oplossings moet weggegooi word.
Moenie TRAKEZE gebruik as u sien dat die oplossing nie helder of vry van deeltjies is nie.
Moet nie na die vervaldatum, wat op die etiket en karton aangedui word, gebruik nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Verpakkingsinhoud en ander inligting
Wat TRAKEZE bevat:
Die aktiewe bestanddeel is rokuroniumbromied .
1 mL bevat rokuroniumbromied 10 mg.
Elke flessie het 'n totale inhoud van rokuroniumbromied 50 mg per 5 mL oplossing.

Die ander bestanddele is asynsuur (vir pH aanpassing), natriumasetaat-trihidraat, natriumchloried, natriumhidroksied (vir pH aanpassing) en water vir inspuitings.

Hoe TRAKEZE lyk en die verpakkingsinhoud
TRAKEZE is 'n deursigtige, kleurlose tot 'n bleek bruin-gelerige oplossing.

Verpakkingshoeveelheid:
Die produk word verpak in 'n deursigtige Tipe-I 10 mL glasflessie wat 5 mL oplossing bevat, met 'n 20 mm flessie-nek, geseël met 'n bromobutiel-rubberprop en 'n polipropileen-afwipdekseltjie.
Kartonhouers bevat 10 flessies elk.
Nie alle verpakkingshoeveelhede word noodwendig bemark nie.

Eienaar van die registrasiesertifikaat
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