PATIENT INFORMATION LEAFLET

TRAKEZE

SCHEDULING STATUS: S4

TRAKEZE 10 mg/ml solution for injection/infusion

Rocuronium bromide

Sugar 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.

What is in this leaflet

1. What TRAKEZE is and what it is used for
2. What you need to know before you use TRAKEZE
3. How to use TRAKEZE
4. Possible side effects
5. How to store TRAKEZE
6. Contents of the pack and other information

1. What TRAKEZE is and what it is used for

Rocuronium bromide belongs to 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 to 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 use TRAKEZE

TRAKEZE should not be administered to you:

- if you are allergic (hypersensitive) to rocuronium bromide or the bromide ion, or any ingredient of TRAKEZE (listed in section 6).

TRAKEZE is contraindicated in new-born 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 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 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)

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 to 1 month).

Other medicines and TRAKEZE

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

Please tell your doctor or pharmacist if you are taking, or have recently taken or used:

- Corticosteroids (such as dexamethasone in the long-term use for asthma or inflammation)
- Antibiotics, such as lincomycin, clindamycin and penicillins
- Lithium (may be used for certain psychiatric disorders)
- Local anaesthetics such as lidocaine or bupivacaine
- Medicines used for the treatment of 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 used for epilepsy treatment (such as phenytoin, carbamazepine)
- Potassium chloride
- Calcium chloride
- 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 or inhalational anaesthetics), other muscle relaxants. Your doctor will take this into account when deciding on a suitable dose of TRAKEZE for you.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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.

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.

3. How TRAKEZE will be administered to you

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.

The usual dose is 0,6 mg per kg body weight and its effect will last 30 to 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 to 23 months), children (2 to 14 years) and adolescents (12 to 18 years). There is inadequate data to support the use of TRAKEZE in neonates (0 to 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 over-dosage your doctor will manage the over-dosage.

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 receiving TRAKEZE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately:

- 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.

Tell your doctor if you notice any of the following:

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 or rash
- 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
- Breathing (respiratory) failure
- Temporary cessation of breathing (apnoea)

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 "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TRAKEZE.

5. How to store TRAKEZE

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, after which it should be discarded. TRAKEZE should not be placed back in the refrigerator, once it has been kept outside. 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 to 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 label and carton.

Return all unused medicines 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 10 mg of rocuronium bromide.

Each vial has a total content of 50 mg rocuronium bromide.

The **other ingredients** are acetic acid, sodium acetate trihydrate, sodium chloride 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 pack sizes may be marketed.

Holder of Certificate of Registration

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