APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ROPIVACAINE 2 mg/ml INFUSION FRESENIUS Solution for infusion
ROPIVACAINE 2mg/ml INJECTION FRESENIUS Solution for injection
ROPIVACAINE 5 mg/ml INJECTION FRESENIUS Solution for injection
ROPIVACAINE 7,5 mg/ml INJECTION FRESENIUS Solution for injection
ROPIVACAINE 10 mg/ml INJECTION FRESENIUS Solution for injection

Ropivacaine hydrochloride

Sugar-free

Please read this leaflet carefully before ROPIVACAINE FRESENIUS is administered to you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, nurse, pharmacist or other healthcare provider.

What is in this leaflet

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

1. What ROPIVACAINE FRESENIUS is and what it is used for

Ropivacaine hydrochloride belongs to a group of medicines called local anaesthetics (numbing medicine).

This medicine stops the nerves from being able to pass pain messages to the brain. It will stop you feeling pain, heat or cold in where it is used. However, you may still be able to experience other feelings such as pressure or touch.

ROPIVACAINE 2 mg/ml, 7,5 mg/ml and 10 mg/ml INJECTION FRESENIUS is used in adults to:

- Numb (anaesthetise) parts of the body during minor and major surgery, including having a baby by Caesarean section.
- Relieve acute pain, for example during childbirth, before or after surgery, or after an accident.

ROPIVACAINE 2 mg/ml and 5 mg/ml INJECTION FRESENIUS is used in children (1 - 12 years of age) to:

- relieve pain before and during operations. This applies to the ROPIVACAINE FRESENIUS 2 mg/ml and 5 mg/ml presentations only.

2. What you need to know before ROPIVACAINE FRESENIUS is administered to you

ROPIVACAINE FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to ropivacaine or any of the other ingredients of ROPIVACAINE FRESENIUS (listed in section 6)
- if you are allergic to any other local anaesthetics of the amide type (such as lidocaine (lignocaine) or bupivacaine)
- into a blood vessel, spine, or joint to numb a specific area of your body, or into the neck of the womb to relieve pain during childbirth
- if you have a decreased amount of blood (hypovolaemia)
- if you have inflammation and/or an infection at the skin area where the injection is to be given.

ROPIVACAINE FRESENIUS 7,5 mg/ml and 10 mg/ml should not be used in children below the age of 12 years as safety and efficacy have not been established.

Warnings and precautions

Regional anaesthetic procedures should always be performed in a properly equipped and staffed area, where adequate life-saving equipment, including oxygen, is available if needed.

Special care should be taken with ROPIVACAINE FRESENIUS:

Special care should be taken to **avoid any injection** of ROPIVACAINE FRESENIUS **directly into a blood vessel** to prevent any immediate toxic effects.

Tell your doctor or healthcare provider before being given the injection:

- if you have problems with your lungs (respiratory function)
- if you have heart problems
- if you are treated with anti-dysrhythmic medicines (medicines used for irregular heartbeat) such as amiodarone as the cardiac effects may be more pronounced (see "Other medicines and ROPIVACAINE FRESENIUS")
- if you are treated with anticoagulant medicines such as low molecular weight heparins and heparinoids
- if you are treated with non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen as blood clotting may be affected
- if you have lost body fluids (low blood volume)
- if you are in a poor general condition due to your age or other factors
- if you have liver problems
- if you have kidney problems
- if you are taking fluvoxamine (an antidepressant) or enoxacin (an antibiotic) as prolonged administration of ROPIVACAINE FRESENIUS should be avoided if you take these medicines
- if you have porphyria (problems with building up red blood pigment, sometimes resulting in neurological symptoms), or if anyone in the family has it. Your doctor may need to use another anaesthetic.

Children

Ropivacaine 2 mg/ml Injection Fresenius

Take special care in children younger than 12 years of age as some injections of ROPIVACAINE FRESENIUS 2 mg/ml to numb parts of the body have not been established in younger children.

Ropivacaine 7,5 mg/ml Injection Fresenius and Ropivacaine 10 mg/ml Injection Fresenius
Take special care in children up to and including 12 years of age. Other strengths (2 mg/ml, 5 mg/ml) may be more appropriate.

Other medicines and ROPIVACAINE FRESENIUS

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

Tell your doctor if you take or use:

- Other local anaesthetics (medicines with a numbing effect)
- Medicines used to treat an uneven heartbeat (arrhythmia), such as lidocaine, mexiletine, amiodarone
- Strong pain killers, such as morphine or codeine.

Your doctor needs to know about these medicines to be able to work out the correct dose of ROPIVACAINE FRESENIUS for you.

Also tell your doctor if you are taking any of the following medicines:

- Medicines for depression (such as fluvoxamine);
- Antibiotics to treat infections (such as enoxacin);
- Ketoconazole (an antifungal medicine).

This is because your body takes longer to get rid of ROPIVACAINE FRESENIUS if you are taking these medicines. If you are taking any of these medicines, prolonged use of ROPIVACAINE FRESENIUS should be avoided.

Pregnancy and breastfeeding

The safe use of ROPIVACAINE FRESENIUS during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, nurse, pharmacist or other healthcare provider for advice before receiving ROPIVACAINE FRESENIUS.

Driving and using machines

ROPIVACAINE FRESENIUS may make you feel drowsy and affect your reaction speed. After you have been given ROPIVACAINE FRESENIUS, do not drive or use machinery until the next day.

ROPIVACAINE FRESENIUS contains salt (as sodium chloride)

ROPIVACAINE 2 mg/ml INJECTION FRESENIUS or ROPIVACAINE 2 mg/ml INFUSION FRESENIUS contains 3,4 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,17 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.
ROPIVACAINE 5 mg/ml INJECTION FRESENIUS contains 3,17 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,15 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.

ROPIVACAINE 7,5 mg/ml INJECTION FRESENIUS contains 2,99 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,15 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.

ROPIVACAINE 10 mg/ml INJECTION FRESENIUS contains 2,8 mg sodium (main component of cooking/table salt) per ml. This is equivalent to 0,14 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.

Tell your doctor if you are on a controlled sodium diet.

3. How ROPIVACAINE FRESENIUS is administered to you

You will not be expected to give yourself ROPIVACAINE FRESENIUS. It will be given to you by a doctor who is qualified to do so.

ROPIVACAINE FRESENIUS may not be injected into a vein, as it may cause serious side effects (see POSSIBLE SIDE EFFECTS).

ROPIVACAINE FRESENIUS will be given to you either as an injection or infusion in a facility with all the necessary emergency equipment and oxygen. Your doctor will decide on the dose; it will depend on the type of pain relief required, your body size, age and health.

For relief of pain (analgesia), the 2 mg/ml concentration may be used. It will depend on what it is used for and also on your health, age and weight.

For numbing of pain (anaesthesia), the smallest dose that can produce effective numbing of the required area should be used. The usual dose is:

Adults and adolescents older than 12 years of age:
2 mg to 300 mg of ROPIVACAINE FRESENIUS.

In infants and children (1 - 12 years of age) the usual dose is 2 - 3 mg ROPIVACAINE FRESENIUS for each kilogram body weight.

The part of the body where it will be used will depend on why you are being given ROPIVACAINE FRESENIUS. Your doctor will give you ROPIVACAINE FRESENIUS in one of the following places:

- The part of the body that needs to be numbed.
- Near to the part of the body that needs to be numbed.
- In an area away from the part of the body that needs to be numbed. This is the case if you are given an epidural injection (into the area around the spinal cord).

When ROPIVACAINE FRESENIUS is used in one of these ways, it stops the nerves from being able to pass pain messages to the brain. It will stop you feeling pain, heat or cold in where it is used. However, you may still be able to experience other feelings such as pressure or touch.
Your doctor will know the correct way to give ROPIVACAINE FRESENIUS to you.

Duration of treatment
Administration of ROPIVACAINE FRESENIUS solution for injection usually takes between 2 to 10 hours in case of anaesthesia prior to certain surgeries and can take up to 72 hours in case of pain relief during or after surgery.
Administration of ROPIVACAINE FRESENIUS solution for infusion usually takes between 0,5 to 6 hours but can take up to 72 hours in case of pain relief during or after surgery.

If you receive more ROPIVACAINE FRESENIUS than you should

Since a healthcare provider will administer ROPIVACAINE FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

The first signs of being given too much ROPIVACAINE FRESENIUS are usually as follows:

- problems with hearing and sight (vision)
- numbness of lips, tongue and around the mouth
- dizziness or light-headedness
- tingling
- speech disorder characterised by difficulty in speaking (dysarthria)
- muscular stiffness, muscular twitching, fits (convulsions)
- low blood pressure
- slow or irregular heartbeat.

These symptoms may be signs of a heart attack (cardiac arrest) and cause you to stop breathing or have severe fits.

To reduce the risk of serious side effects, your doctor will stop giving you ROPIVACAINE FRESENIUS as soon as these signs appear. If any of these happen to you, or you think you may have received too much ROPIVACAINE FRESENIUS, **tell your doctor or healthcare professional immediately.**

If you forget to use ROPIVACAINE FRESENIUS:

Since a healthcare provider will administer ROPIVACAINE FRESENIUS, it is unlikely that the dose will be missed.

Do not receive a double dose to make up for forgotten individual doses.

If you stop using ROPIVACAINE FRESENIUS

Your doctor will decide when your treatment should be stopped.

4. Possible side effects

ROPIVACAINE FRESENIUS can have side effects.

Not all side effects reported for ROPIVACAINE FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ROPIVACAINE FRESENIUS, please consult your healthcare provider for advice.

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

- Swelling of the face, lips, tongue, or throat, difficulty in swallowing or breathing (angio-oedema);
- Rash, itchy/lumpy rash (urticaria).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ROPIVACAINE FRESENIUS. You will be under continued observation and your doctor will treat you immediately.

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- Pins and needles (paraesthesia)
- Feeling dizzy
- Headache
- Slow or fast heartbeat (bradycardia, tachycardia)

- Low or high blood pressure
- Nausea and vomiting
- Difficulty in passing urine
- Back pain
- High body temperature (fever), chills
- Difficulty passing urine.

Less frequent:

- Anxiety
- Decreased sensitivity or feeling in the skin (hypoaesthesia)
- Some symptoms can occur if the infusion was given into a blood vessel by mistake, or if you have been given too much ROPIVACAINE FRESENIUS. These include fits (seizures), feeling dizzy or light-headed, numbness of the lips and around the mouth, numbness of the tongue, hearing problems, problems with your sight (vision), problems with your speech, stiff muscles and trembling (see **If you have been given too much ROPIVACAINE FRESENIUS**)
- Fainting (syncope)
- Difficulty in breathing (dyspnoea)
- Low body temperature (hypothermia)
- Heart attack (cardiac arrest)
- Uneven heartbeat (dysrhythmias)
- Numbness due to nerve irritation caused by the needle or injection
- Involuntary muscle movements (dyskinesia).

Possible side effects seen with other local anaesthetics which may also be caused by ROPIVACAINE FRESENIUS include:

- Total spinal block may occur if an epidural dose is inadvertently administered intrathecally (into the spinal canal).
- Numbness, due to nerve irritation caused by the needle or the injection. This does not usually last for long.
- Damaged nerves. This may cause permanent problems.

Additional side effects in children

In children, the side effects are the same as in adults except for low blood pressure which happens less often in children and vomiting, which happens more often in children.

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 ROPIVACAINE FRESENIUS.

5. How to store ROPIVACAINE FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 ºC. Protect from light.

Do not use after the expiry date stated on the label/ carton.

Do not refrigerate or freeze.

ROPIVACAINE FRESENIUS is for single use only. Discard any unused portion.

The healthcare provider is responsible for the safe disposal of any unused ROPIVACAINE FRESENIUS**.** Medicines should not be disposed of in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ROPIVACAINE FRESENIUS contains

- The active substance is ropivacaine hydrochloride.

  ROPIVACAINE 2mg/ml INJECTION FRESENIUS: Each ampoule of 10 ml solution for injection contains 20 mg ropivacaine hydrochloride. Each ampoule of 20 ml solution for injection contains 40 mg ropivacaine hydrochloride.

  ROPIVACAINE 5 mg/ml INJECTION FRESENIUS: Each ampoule of 10 ml solution for injection contains 50 mg ropivacaine hydrochloride.

  ROPIVACAINE 7,5 mg/ml INJECTION FRESENIUS**:** Each ampoule of 10 ml solution for injection contains 75 mg ropivacaine hydrochloride. Each ampoule of 20 ml solution for injection contains 150 mg ropivacaine hydrochloride.

  ROPIVACAINE 10 mg/ml INJECTION FRESENIUS**:** Each ampoule of 10 ml solution for injection contains 100 mg ropivacaine hydrochloride. Each ampoule of 20 ml solution for injection contains 200 mg ropivacaine hydrochloride.

  ROPIVACAINE 2 mg/ml INFUSION FRESENIUS solution for infusion: Each 100 ml bag contains 200 mg ropivacaine hydrochloride. Each 200 ml bag contains 400 mg ropivacaine hydrochloride.

- The other ingredients are sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injection.

What ROPIVACAINE FRESENIUS looks like and contents of the pack

ROPIVACAINE FRESENIUS 2 mg/ml, 5 mg/ml, 7,5 mg/ml and 10 mg/ml solution for injection are sterile, clear, colourless solutions free of particles.

ROPIVACAINE FRESENIUS 2 mg/ml solution for infusion is a sterile, clear, colourless solution, free of particles.

ROPIVACAINE 2 mg/ml INJECTION FRESENIUS is available in a 10 ml and 20 ml transparent blow moulded polypropylene ampoule (*Ovalia)* with an integrated Luer-lock fitting.

ROPIVACAINE 5 mg/ml INJECTION FRESENIUS is available in a 10 ml transparent blow moulded polypropylene ampoule (*Ovalia*), with an integrated Luer-lock fitting.

ROPIVACAINE 7,5 mg/ml INJECTION FRESENIUS is available in a 10 ml and 20 ml transparent blow moulded polypropylene ampoule (*Ovalia*), with an integrated Luer-lock fitting.

ROPIVACAINE 10 mg/ml INJECTION FRESENIUS is available in a 10 ml and 20 ml transparent blow moulded polypropylene ampoule (*Ovalia*), with an integrated Luer-lock fitting.

ROPIVACAINE 2 mg/ml INFUSION FRESENIUS is available in a 100 ml or 200 ml transparent, polyolefin bag (***Free****flex*®), with an infusion port and injection port consisting of a polypropylene housing and an overpouch based on polyolefins.

1, 5, 10 ampoule(s) are packed in a blister pack. All the ampoules are packed in an outer carton.

Each *Free**flex*® bag is packed in an overwrap pouch.

Not all pack sizes may be available.

Holder of Certificate of Registration

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ROPIVACAINE 5 mg/ml INJECTION FRESENIUS: 46/4/0901

ROPIVACAINE 7,5 mg/ml INJECTION FRESENIUS: 46/4/0902

ROPIVACAINE 10 mg/ml INJECTION FRESENIUS: 46/4/0903

Access to the corresponding professional information

The professional information will be printed and supplied with the injection/infusion