# **Ropivacaine-AFT**

Ropivacaine hydrochloride 2 mg/mL (0.2%) Solution for infusion

### What is in this leaflet

Please use this leaflet carefully before you are given Ropivacaine-AFT.

This leaflet answers some common questions about Ropivacaine-AFT. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Ropivacaine-AFT against the benefits they expect it will have for you.

#### If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with you. You may need to read it again.

#### What Ropivacaine-AFT is used for

Ropivacaine-AFT is a local anaesthetic (an-es-thet-ic). It is injected into the body where it makes the nerves unable to pass messages to the brain. Depending on the amount used, Ropivacaine-AFT will either totally stop pain or will cause a partial loss of feeling.

Ropivacaine-AFT is used as an anaesthetic to stop the pain of surgery and/or to make childbirth less painful. Ropivacaine-AFT is also used after surgery to treat post-operative pain.

Your doctor may have prescribed Ropivacaine-AFT for another reason. Your doctor will have explained why you are being treated with Ropivacaine-AFT and told you what dose you will be given.

Ask your doctor if you have any questions about why Ropivacaine-AFT have been prescribed for you.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

#### Before you are given Ropivacaine-AFT

#### When you must not be given it

Ropivacaine-AFT must not be used if:

- you have any allergies to:
  - any ingredient listed at the end of this leaflet
  - any other local anaesthetics.
- you have problems controlling your low blood pressure
- you have inflammation and/or an infection at the site of injection.

#### Before you start to use it

Tell your doctor if:

- you have any allergies to other substances
- you have or have had any of these medical conditions:
  - problems with your blood pressure or circulation
    - blood poisoning
    - problems with the clotting of your blood
    - acidosis, or too much acid in the blood

- nerve problems
- liver problems
- kidney problems
- problems with your heart
- disease of the brain or spine, including meningitis, polio, cancer or infections
- muscle disease or weakness (e.g. myasthenia gravis)
- porphyria (rare disorders that affect mainly the skin or nervous system and may cause abdominal pain)
- you are pregnant, are breastfeeding or intend to breast-feed.

Your doctor will discuss the possible risks and benefits of using Ropivacaine-AFT during pregnancy and breast-feeding.

It may not be safe for you to be given Ropivacaine-AFT if you have any of these conditions.

Ropivacaine-AFT will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

If you have not told your doctor about any of the above, tell them before you start your treatment Ropivacaine-AFT.

# Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are receiving Ropivacaine-AFT.

Some medicines may interfere with Ropivacaine-AFT. These include:

- local anaesthetics, like lignocaine and mexiletine
- medicines that control your heart beat, like amiodarone
- medicines used to thin the blood, including aspirin
- low molecular weight heparin or other medicines used to prevent blood clots
- fluvoxamine, a medicine used to treat depression.
- enoxacin, a medicine used to treat bacterial infections.
- · ketoconazole, a medicine used to treat fungal infections
- cimetidine, a medicine used to treat stomach ulcers or heartburn
- medicines for depression.

These medicines may be affected by Ropivacaine-AFT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while being given Ropivacaine-AFT.

# How Ropivacaine-AFT is given

Overall treatment with Ropivacaine-AFT must be done under the supervision of a doctor. Your treatment with Ropivacaine-AFT may be given by a healthcare professional (e.g. doctor or nurse) experienced in the administration of local anaesthetics (see *How it is given*).

# How much is given

Your doctor will decide what dose you will receive, as well as when and for how long you will receive it. The dose will be determined by your body size, age and the type of pain relief required. Your doctor will have had a lot of experience using Ropivacaine-AFT or other local anaesthetics and will choose the best dose for you. It will also depend on factors such as kidney function, liver function and other medicines you are being given.

# Ask your doctor if you want to know more about the dose of Ropivacaine-AFT you receive.

# How it is given

Ropivacaine-AFT will be given to you by an injection into the skin, near a single nerve, or into an area which contains a large number of nerves; it may also be directed into a surgical incision after surgery by a tube. Ropivacaine-AFT it should not be injected directly into the blood.

Once Ropivacaine-AFT is given, it will result in an area of numbness at or near the site of administration, or in an area that may seem unrelated to the site of administration. The latter will be the case is you are given an epidural injection (an injection around the spinal cord).

# While you are being given Ropivacaine-AFT

# Things to be careful of

**Be careful driving or operating machinery after you have been given Ropivacaine-AFT.** You may be drowsy and your reflexes may be slow.

**Do not drink alcohol while you are being given Ropivacaine-AFT.** Your blood pressure may drop, making you feel dizzy and faint.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

# In case of overdose

#### If too much is given (overdose)

Since Ropivacaine-AFT is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you are particularly sensitive to Ropivacaine-AFT, or the dose is accidentally injected directly into your blood, you may develop problems with your sight, hearing, and get a numb feeling in or around the mouth, feel dizzy or stiff, or have twitchy muscles. Tell your doctor or nurse immediately. You may need urgent medical attention.

In rare cases, these effects may be followed by drowsiness and fits. In extreme cases you may have problems with your breathing or your heart and you may become unconscious.

# Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Ropivacaine-AFT.

Like other medicines, Ropivacaine-AFT can cause some side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have. **Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with Ropivacaine-AFT.** 

Tell your doctor if you notice any of the following and they worry you:

- nausea (feeling sick)
- vomiting
- headache
- dizziness
- irregular or slow heart beat
- fever
- a tingling feeling ("pins and needles")
- shivering
- difficulty passing urine.

These are all mild side effects of Ropivacaine-AFT.

# Tell your doctor or nurse immediately if you notice any of the following:

- stiff or twitching muscles
- painful joints
- difficulty breathing
- extreme dizziness
- slow heart beat
- pain in the chest
- fits
- on rare occasions you may lose consciousness.

# These are all serious side effects. You may need urgent medical attention.

Serious side effects are rare.

Other adverse effects not listed here may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

# After being given Ropivacaine-AFT

# Storage

Ropivacaine-AFT is stored in the pharmacy or in the ward. It is kept in a cool dry place where the temperature stays below 25 °C; it is not refrigerated or frozen.

Store all medicine out of reach of children.

# Disposal

The hospital staff will dispose of any leftover Ropivacaine-AFT.

# Product description

# What Ropivacaine-AFT look like:

Ropivacaine-AFT is a clear, colourless, sterile and isotonic solution for infusion. The solution is filled into colourless preprinted latex free plastic bags of 100 mL and 200 mL. Each bag is wrapped in a plastic foil overbag, for single use in one patient only. Each carton contains 10 bags.

# Ingredients:

Active ingredient:

• Ropivacaine hydrochloride 2 mg/mL (0.2%)

# Inactive ingredients:

- Sodium chloride
- Hydrochloric acid
- Sodium hydroxide
- Water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine, dyes or any preservatives.

# Sponsor details

Ropivacaine-AFT is supplied in New Zealand by:

AFT Pharmaceuticals Ltd Level 1, 129 Hurstmere Road Takapuna Auckland 0622 NEW ZEALAND

Phone:0800 423 823Email:customer.service@aftpharm.com

# Date of preparation

This leaflet was prepared in October 2021.