

Fraxiparine® Injection

nadroparin calcium
9,500 IU anti-Xa / mL solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fraxiparine injections. It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or nurse.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Fraxiparine against the benefits they expect it will have for you.

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

Keep this leaflet with the injection.

You may need to read it again.

What Fraxiparine is used for

Fraxiparine belongs to a group of medicines called Low Molecular Weight Heparins.

Fraxiparine is used to prevent the blood from clotting after having surgery, during haemodialysis, during hospitalisation for acute illness or in intensive care unit with extended bed rest and is also used to treat existing blood clots that are blocking blood vessels.

It is a medicine that works by delaying the action by which blood clots form. This results in the blood remaining thin and prevents formation of clots which may become lodged in blood vessels and treats blood clots if they have already formed.

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

There is not enough information to recommend how the use of this medicine can affect your ability to drive a car or operate machinery.

There is not enough information to recommend the use of this medicine for patients aged less than 18 years. Therefore, Fraxiparine is not recommended for use in children or adolescents.

Before you use Fraxiparine

When you must not use it

Do not use Fraxiparine if you have an allergy to:

- any medicine containing nadroparin calcium
- heparin or low-molecular weight heparins
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use Fraxiparine if you:

- have had thrombocytopenia (a low blood platelet count) due to using Fraxiparine before
- have an increased risk of bleeding or a bleeding disorder
- have a history of ulcers in the stomach or intestine

- have had a burst blood vessel in your brain
- have infective endocarditis (an infection of the lining of the heart)
- have severe kidney failure and are being treated for a blood clot

Do not use this medicine after the expiry date printed on the carton or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Do not take this medicine if you are pregnant or planning to become pregnant unless you and your doctor have discussed the risks and benefits involved.

It is not known whether Fraxiparine can harm your baby if used during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in Fraxiparine can pass into breast milk. The effect on the baby is not known; therefore Fraxiparine should not be used when you are breast-feeding.

Tell your doctor if you have or have had any of the following medical conditions or procedures:

- an increased risk of bleeding including:
 - liver problems or liver failure
 - very high blood pressure
 - history of stomach ulcers

- bleeding disorders
- disorder of the blood vessels in the eye
- recent surgery of the brain, spinal cord or eye
- kidney disease
- problems with your heart including angina or heart attack
- high potassium levels in the blood
- diabetes
- metabolic acidosis (too much acid in the blood)
- thrombocytopenia (a low blood platelet count)
- a recent or planned spinal or epidural injection (an injection around the spinal cord)
- an allergy to latex, as the needle shield of the syringe may contain latex
- dead skin tissue (cutaneous necrosis) around injection sites

Tell your doctor if you are elderly or aged less than 18 years.

If you have not told your doctor about any of the above, tell him/her before you start taking Fraxiparine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Fraxiparine may interfere with each other.

These include:

- aspirin or other medicines used to reduce pain and inflammation (non steroidal anti-inflammatory drugs or salicylates)
- ticlopidine or other medicines used to thin the blood and prevent it from clotting (oral anticoagulants and anti-platelet agents)
- corticosteroids (medicines used to reduce inflammation)
- dextrans (medicines used to thin the blood)

- ACE inhibitors (medicines used to treat high blood pressure and some other heart conditions)

These medicines may be affected by Fraxiparine 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Fraxiparine is given

The dose of Fraxiparine you will need will depend on why you are being treated with Fraxiparine and also on your body weight.

If you are injecting this medicine yourself you will be instructed by your doctor, nurse or pharmacist on how to prepare and give the injection subcutaneously (under the skin). Use it exactly as prescribed and do not exceed the prescribed dosage.

How much to take and how long to take Fraxiparine for

Prevention of blood clots:

For the general prevention of blood clots, Fraxiparine will be given by an injection subcutaneously (under the skin), as a single daily dose of 0.3 mL (2,850 IU anti-Xa) for at least 7 days or as directed by your doctor. For most surgical patients the first dose should be given 2 to 4 hours before surgery.

If you are to have orthopaedic surgery, the first doses will be given 12 hours before surgery and 12 hours after the end of surgery. This dose and the doses given afterwards will be calculated by your doctor according to your body weight.

Treatment should be for at least 10 days or as directed by your doctor.

If you have moderate or severe kidney impairment, you may need a reduced dose.

Follow your doctor's instructions on how much Fraxiparine should be taken.

Treatment of existing blood clots:

For the treatment of existing blood clots, Fraxiparine will be given by an injection subcutaneously (under the skin) twice daily for 10 days. The dose will be calculated by your doctor according to your body weight.

If you have moderate or severe kidney impairment, you may need a reduced dose.

Follow your doctor's instructions on how much Fraxiparine should be taken.

Prevention of clotting during haemodialysis:

For prevention of clotting during haemodialysis, Fraxiparine is usually given as a single dose into the arterial line of the haemodialysis machine at the start of each session. This dose will be calculated by your doctor according to your body weight. An extra smaller dose may be given during dialysis for sessions lasting longer than 4 hours.

Prevention of clotting during hospitalisation with extended bed rest:

For the prevention of clotting during hospitalisation with extended bed rest (for at least 3 days), Fraxiparine will be given by an injection subcutaneously (under the skin), as a single daily dose. The dose will be calculated by your doctor according to your body weight.

Follow your doctor's instructions on how much and how long Fraxiparine should be taken.

How to self-administer Fraxiparine

In some cases, you may be allowed to treat yourself with Fraxiparine. You should follow the guidelines below to make sure that you inject

Fraxiparine properly. You should speak with your doctor if you have any concerns about how to give the injection. Most people, however, will be given the injection by a nurse or doctor.

Removal of packaging prior to injection:

To divide the syringes, carefully fold the twin pack several times, so that the syringes are back to back, then slowly using an even pressure divide the two syringes starting from the plunger end of the pack.

To remove the syringe from its plastic packaging, gently tear the top backing film completely from the plastic tray (starting from the plunger end), then allow the syringe to roll onto the palm of your other hand.

The rubber cap over the needle may appear to be off-centre on the syringe, however, this occurs during packaging and does not mean that the needle is bent.

Preparation of syringe for subcutaneous injection:

To remove the cap from the syringe needle:

- hold the syringe vertically (grey cap uppermost)
- hold the grey cap by its collar, and the syringe barrel in your other hand, then slowly rotate the syringe barrel gently pulling downwards at the same time, until the needle is fully withdrawn from the cap
- do not pull the cap upwards from the syringe - this may bend the needle

Fraxiparine 0.2 mL, 0.3 mL and 0.4 mL prefilled syringes are intended for administration of whole doses only. The entire contents of the syringe should be injected. There may be a small air bubble in the syringe but this does not have to be removed.

Fraxiparine 0.6 mL, 0.8 mL and 1.0 mL prefilled graduated syringes may be used to administer adjusted dosages. Hold the syringe vertically

with the needle uppermost and ensure the air bubble is at the top of the syringe. Advance the plunger to the volume/dosage required, expelling air and any excess.

Any unused portion of Fraxiparine should be disposed of at once.

Method for subcutaneous administration:

- A suitable site for injection is the skin on the lower part of the stomach, away from any wound or joints. Alternatively injection may be made into the thigh.
- Pinch a skin fold. Note: the use of alcohol may toughen the skin, making later injection difficult.
- Maintain the fold and insert the needle vertically to its full depth then inject Fraxiparine over 10 to 15 seconds. There may be a small air bubble in the barrel of the syringe but this does not have to be removed.
- Still holding the skin fold, withdraw the needle vertically. Do not rub the site of injection.
- After the injection is given, install the safety system on the Fraxiparine syringe and dispose of carefully.

Fraxiparine is not intended for injection directly into the muscle.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Fraxiparine.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Increased or excessive bleeding is the major sign of overdose. Overdose may be treated by reducing or delaying the next doses of Fraxiparine or in more serious cases, a drug called protamine sulphate can partly reverse the effect of Fraxiparine.

While you are using Fraxiparine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Fraxiparine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Fraxiparine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Fraxiparine affects you.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while being treated with Fraxiparine.

Like other medicines, Fraxiparine can cause some side effects. Sometimes they are serious, most of

the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

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

More common side effects:

- small blood clot under the skin at the injection site
- abnormal bleeding
- injection site reactions

Less common side effects:

- rash, hives, redness or itching around the injection site
- calcium deposits at the injection site
- dead skin tissue (cutaneous necrosis) at the injection site

Your doctor may monitor you with blood tests for:

- high levels of proteins
- high levels of potassium
- low platelet count or raised white blood cell count
- high levels of some liver enzymes

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reactions such as skin rash, swelling of the face including mouth, lips and/or tongue, throat, wheezing and shortness of breath
- persistent painful erection of the penis (priapism)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using Fraxiparine

Storage

Fraxiparine should be stored below 25°C. Do not freeze. Do not refrigerate, as cold injections may be painful.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Use Fraxiparine once only and discard any unused portion of each syringe.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Fraxiparine is a sterile solution for subcutaneous injection.

Fraxiparine is presented as 0.2 mL, 0.3 mL, and 0.4 mL unit dose syringes and 0.6 mL, 0.8 mL and 1.0 mL graduated syringes. 0.2 mL, 0.3 mL, 0.4 mL and 0.6 mL syringes come in packs of 2 and 10 syringes. 0.8 mL and 1.0 mL syringes come in packs of 10 syringes.

Ingredients

Fraxiparine contains nadroparin calcium 9,500IU anti-Xa per 1.0 mL as the active ingredient.

- water for injections
- calcium hydroxide or dilute hydrochloric acid

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

Suppliers

Fraxiparine is supplied in Australia by:

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St. Leonards, 2065, NSW.

Fraxiparine® is a registered trade mark of Aspen Global Inc.

0.2 mL Syringe AUST R 51308

0.3 mL Syringe AUST R 51309

0.4mL Syringe AUST R 51310

0.6 mL Syringe AUST R 51311

0.8 mL Syringe AUST R 51312

1.0 mL Syringe AUST R 51313

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