

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

FRAXIPARINE 0,2 ml

FRAXIPARINE 0,3 ml

FRAXIPARINE 0,4 ml

FRAXIPARINE 0,6 ml

FRAXIPARINE 0,8 ml

FRAXIPARINE 1 ml

Sterile solution for injection

Nadroparin calcium

Sugar free

Read all of this leaflet carefully before you start using FRAXIPARINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FRAXIPARINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FRAXIPARINE is and what it is used for
2. What you need to know before you take FRAXIPARINE
3. How to take FRAXIPARINE

4. Possible side effects
5. How to store FRAXIPARINE
6. Contents of the pack and other information

1. What FRAXIPARINE is and what it is used for

FRAXIPARINE is called an antithrombotic medicine.

FRAXIPARINE is a medicine that helps to prevent blood clots from forming in the blood vessels (thromboses), which may lead to blood clots in the chest (pulmonary embolism) in patients undergoing hip or knee replacement surgery or abdominal surgery, or treats blood clots if they have already formed.

FRAXIPARINE is used in medical patients that are at high risk (lung failure and/or lung infection and/or heart failure), immobilised due to being very ill or hospitalised in an intensive care unit (ICU).

2. What you need to know before you use FRAXIPARINE

Do not use FRAXIPARINE:

- if you are hypersensitive (allergic) to nadroparin calcium, unfractionated heparin, any other low molecular heparin or to any of the other ingredients of FRAXIPARINE (see section 6) especially when a severe decrease in the number of your blood platelets (cells that help blood to clot) has occurred in recent months.
- if you are bleeding or have any illness which reduces the ability of your blood to clot normally.
- if you have an infection of the heart valves (acute infective endocarditis).
- if you have a condition that is likely to cause bleeding, such as:
 - a stomach ulcer.
 - threatened abortion.

- recent childbirth.
 - severe or uncontrolled high blood pressure.
 - a bulging blood vessel in the brain or heart (cerebral or aortic aneurysm).
 - during or after eye, brain or spinal cord surgery or trauma.
 - prior to lumbar puncture or regional anaesthetic block.
 - surgical or traumatic wounds resulting in large open surfaces.
 - severe inflammation of the blood vessels (vasculitis)
 - active, cavitating tuberculosis.
 - carcinoma (type of cancer) of the internal organs of the body (especially chest or abdomen).
 - primary or secondary brain tumour.
 - inflammation of the lining around the heart (pericarditis).
- if you are being treated for a blood clotting condition and have severe kidney disease.
 - if you have an artificial heart valve (mechanical heart valve prosthesis).
 - if you have severe liver impairment.
 - if you are pregnant or breastfeeding.
 - if you are under 18 years of age.

Warnings and precautions

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

- if you have a history of allergic reactions with heparins or low molecular weight heparins (medication that has been prescribed for you to prevent the formation of blood clots or to treat clots that have already formed).
- if you have any delayed reactions as cross- reactivity may occur, and a delayed hypersensitivity can present.
- if you have a skin reaction at injection site.
- if you have a risk of uncontrolled bleeding (*haemorrhage*) including:
 - history of stomach ulcers.
- if you have kidney or liver disease.
- if you are elderly, especially women over 60 years old.
- if you are taking other medications that affect blood clotting e.g. aspirin, ibuprofen for inflammation and pain.

You will need regular blood tests:

- FRAXIPARINE can cause a reduction in the number of platelets in your blood.
- FRAXIPARINE can increase the potassium levels in your blood. You will need to have blood tests, if you have diabetes, serious kidney disease or if you are taking other medicines that affect potassium levels.

You should go for frequent checks with regards to signs and symptoms of neurological deficits such as back pain, sensory and motor deficits (numbness and weakness of the lower limbs), disturbances of rectal and/or bladder functions. If a neurological disorder is determined, treatment should be started immediately. You should notify your doctor immediately if you experience one of these symptoms.

You will be monitored closely if you are going to have a spinal anaesthetic or fluid removed from the spine area (*spinal lumbar puncture*) as FRAXIPARINE may cause bleeding into the spine at the injection site.

Children and adolescents

FRAXIPARINE is contraindicated in patients aged less than 18 years.

Other medicines and FRAXIPARINE

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

Tell your doctor if you are taking any of the following:

- Other medicines that can affect blood clotting (such as aspirin, dipyridamole, ibuprofen and indomethacin) should not be taken with FRAXIPARINE unless specifically prescribed by your doctor.
- Dextran injections e.g. used for blood clotting.
- Thrombolytic enzymes such as streptokinase e.g. used for blood clotting.
- Digitalis: used to treat certain heart conditions.
- Tetracyclines e.g. doxycycline, lymecycline: used to treat bacterial infections.
- Nicotine.
- Antihistamines e.g. chlorpheniramine, loratadine: e.g. used for allergies and contained in certain cold and flu combinations.
- IV nitroglycerine used in certain heart conditions and high blood pressure.

Pregnancy and breastfeeding

You should not take FRAXIPARINE if you are pregnant or breastfeeding your baby.

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 taking this medicine.

Driving and using machines

FRAXIPARINE has no or negligible influence on the ability to drive and use machines.

You should not drive, use machinery or perform any tasks that require concentration, until you are certain that FRAXIPARINE does not adversely affect your ability to do so.

It is not always possible to predict to what extent FRAXIPARINE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which FRAXIPARINE affects you (see section 4).

3. How to use FRAXIPARINE

Do not share medicines prescribed for you with any other person.

Always use FRAXIPARINE exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you the dose and volume of FRAXIPARINE you need to use, and for how long you need to use it.

Your doctor will tell you how long your treatment with FRAXIPARINE will last. Do not stop treatment early. If you have the impression that the effect of FRAXIPARINE is too strong or too weak, tell your doctor or pharmacist.

How to use FRAXIPARINE:

FRAXIPARINE is given by an injection under the skin (*subcutaneously*) into a skin fold of the lower abdominal area.

While usually a healthcare provider will administer this injection, some patients may be taught how to do this themselves. If you are taught to self administer, you should follow carefully the step-by-step instructions.

Don't inject FRAXIPARINE into muscle.

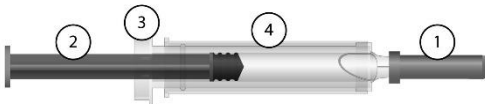
For FRAXIPARINE pre-filled syringes:

The pre-filled syringes are available in different doses. Your doctor will select the correct syringe dose for you. Some people may need to adjust the volume in the syringe. Your doctor will let you know if this applies to you.

Step-by-step instructions

Parts of the syringe:

- ① Needle shield
- ② Plunger
- ③ Finger-grip
- ④ Security sleeve

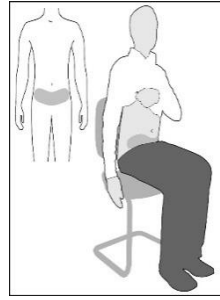


Instructions for use

1. Wash your hands thoroughly with soap and water and dry them with a towel.
2. Remove the syringe from the carton and check that:
 - the expiry date has not passed
 - the syringe has not been opened or damaged.

3. Sit or lie down in a comfortable position.

Choose a place in the lower abdominal (tummy) area, at least 5 cm below your belly button (picture A).



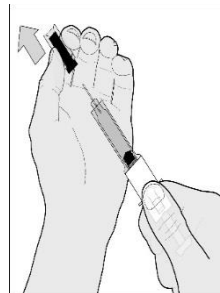
Alternate the left and right side of the lower abdominal area at each injection. This will help to reduce the discomfort at the injection site.

If injecting in the lower abdominal area is not possible, ask your nurse or doctor for advice.

Picture A

4. Clean the injection area with an alcohol wipe.

5. Remove the needle shield, by first twisting it and then pulling it in a straight line away from the body of the syringe (picture B).



Discard the needle shield.

Picture B

If the volume in the syringe is more than you need, you must remove the excess before you inject yourself.

- Hold the syringe with the needle pointing straight down.
- Push the syringe plunger gently down until the bottom of the bubble sits on the line marked

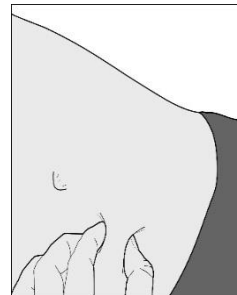
with the volume your doctor has prescribed for you.

- Drip the fluid that comes out of the needle on to a tissue, and discard.
- The syringe is now ready to use.

Important note:

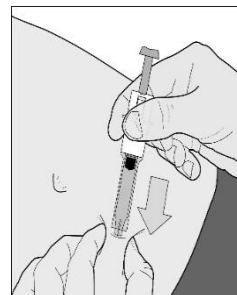
- Don't touch the needle or allow it to touch any surface before the injection
- It is normal to see a small air bubble in this syringe. Don't try to remove this air bubble before making the injection - you may lose some of the medicine if you do.

6. Gently pinch the skin that has been cleaned to make a fold. Hold the fold between the thumb and the forefinger during the entire injection (picture C).



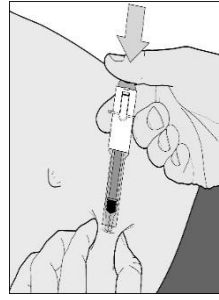
Picture C

7. Hold the syringe firmly by the finger grip. Insert the full length of the needle at right angles into the skin fold (picture D).



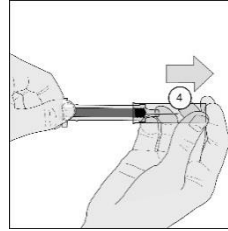
Picture D

8. Inject ALL the contents of the syringe by pressing down on the plunger as far as it goes (picture E). Then gently remove the needle from the skin.



Picture E

9. After the injection, hold the syringe in one hand by gripping the security sleeve, use the other hand to hold the finger grip and pull firmly back. This unlocks the sleeve. Slide the sleeve up the body of the syringe until it locks into position over the needle (picture F).



Picture F

Do not dispose of the used syringe in household waste. Dispose of it as your doctor or pharmacist has instructed.

If you administer more FRAXIPARINE than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FRAXIPARINE

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

If you stop using FRAXIPAXINE

Use FRAXIPARINE for as long as your doctor recommends. Don't stop unless your doctor advises you to.

If you stop the treatment before your doctor tells you to, the blood clot may not be treated properly or you may be at higher risk of developing a new blood clot in a vein of your leg or lung. If you want to stop taking FRAXIPARINE speak to your doctor or pharmacist first.

4. Possible side effects

FRAXIPARINE can have side effects.

Not all side effects reported for FRAXIPARINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FRAXIPARINE, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking FRAXIPARINE and 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,
- rash or itching,
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Bleeding (most common complication),
- bruising easily and feeling extremely tired due to low platelet levels in the blood (thrombocytopenia),

- chest pain, racing heart or irregular heart beat, muscle weakness or numbness in your limbs; this may be a sign of high potassium levels in your blood (hyperkalaemia),
- severe pain, swelling and discoloration due to tissue cell death at the site of injection.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Collection of blood outside the blood vessels, usually in liquid form within the tissue at the injection site,
- reduced liver function (increase in the amount of liver enzymes in the blood, as seen from a blood test).

Less frequent side effects:

- Increase in the number of platelets (blood cells necessary for blood clotting),
- increase in white blood cells (as seen on a blood test result),
- persistent painful erection of the penis,
- risk of thinning of bones (osteoporosis) as well as breaking (fractures),
- hardening of tissue or other material by the deposition of or conversion into calcium compounds at the injection site,
- redness of the skin (erythema),
- high levels of fat in the blood (rebound hyperlipidemia) after stopping treatment with FRAXIPARINE.

Side effects with unknown frequency:

- Headache,
- severe headaches (migraines).

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 Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ /+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of FRAXIPARINE.

5. How to store FRAXIPARINE

Store all medicines out of reach of children

Pre-filled syringes and graduated pre-filled syringes:

Store at or below 25 °C.

Do not freeze.

Discard any unused portion of each syringe.

Do not refrigerate, as the injection of cold injections may be painful. Do not mix with other preparations.

Keep in original packaging until required for use.

Do not store in a bathroom.

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

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 FRAXIPARINE contains

FRAXIPARINE 0,2 ml:

The active substance is 1 900 anti-Xa IU of nadroparin calcium

FRAXIPARINE 0,3 ml:

The active substance is 2 850 anti-Xa IU of nadroparin calcium

FRAXIPARINE 0,4 ml:

The active substance is 3 800 anti-Xa IU of nadroparin calcium

FRAXIPARINE 0,6 ml:

The active substance is 5 700 anti-Xa IU of nadroparin calcium

FRAXIPARINE 0,8 ml:

The active substance is 7 600 anti-Xa IU of nadroparin calcium

FRAXIPARINE 1,0 ml:

The active substance is 9 500 anti-Xa IU of nadroparin calcium

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

What FRAXIPARINE looks like and contents of the pack

Pre-filled syringes and graduated pre-filled syringes:

FRAXIPARINE is a clear to slightly opalescent, colourless or slightly yellow solution.

FRAXIPARINE 0,2 ml

FRAXIPARINE 0,3 ml

FRAXIPARINE 0,4 ml

0,2 ml, 0,3 ml and 0,4 ml: Sterile Solution for Injection in 1 ml unit dose ungraduated pre-filled glass syringes, presented in cartons containing two or ten syringes.

FRAXIPARINE 0,6 ml

FRAXIPARINE 0,8 ml

FRAXIPARINE 1,0 ml

0,6 ml, 0,8 ml and 1,0 ml: Sterile Solution for Injection in 1 ml graduated pre-filled glass syringes, presented in cartons containing two or ten syringes.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 118 088 / +27 (0)11 239-6200

This leaflet was last revised in

26 March 2024

Registration numbers

FRAXIPARINE 0,2 ml: 31/8.2/0576

FRAXIPARINE 0,3 ml: 31/8.2/0577

FRAXIPARINE 0,4 ml: 31/8.2/0578

FRAXIPARINE 0,6 ml: 31/8.2/0579



FRAXIPARINE 0,8 ml: 31/8.2/0580

FRAXIPARINE 1 ml: 31/8.2/0581

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia:	NS2
0,2 ml	05/8.2/0013
0,3 ml	05/8.2/0014
0,4 ml	05/8.2/0016
0,6 ml	05/8.2/0017
0,8 ml	05/8.2/0018
1 ml	05/8.2/0019

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