



A guide for patients **with or at risk of a blood clot**

Treatment and prevention with **FRAGMIN**

Pr **Fragmin**[®]
dalteparin sodium

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- Italian
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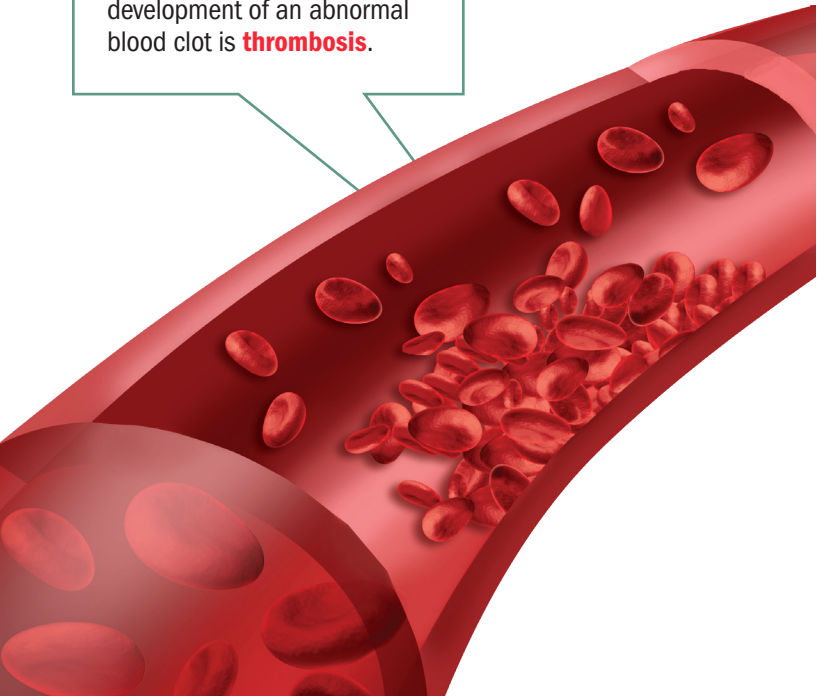


Use this booklet to help you understand why it is important for you to stay on FRAGMIN as prescribed.

What is a Blood Clot?

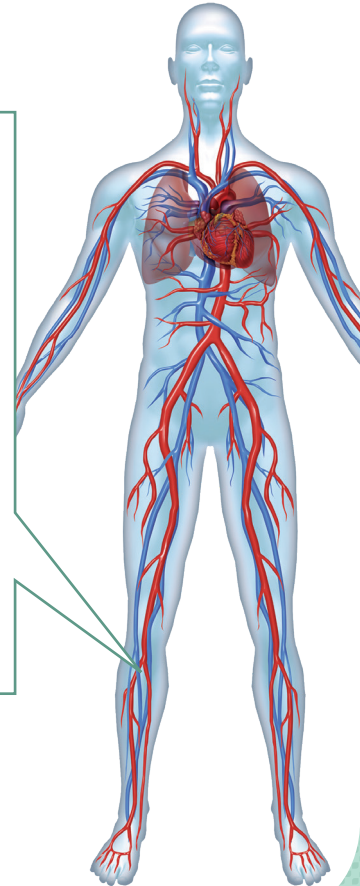
Blood clotting is a normal process of the body to stop the excessive bleeding when a blood vessel is injured.

Sometimes, clots form abnormally within a **blood vessel**. The medical term for development of an abnormal blood clot is **thrombosis**.



What is Deep Vein Thrombosis (DVT)?

- A blood clot that has formed in a **deep vein**.
- DVT mostly occurs in the deep veins of the **legs**, but can also occur in other parts of the body, such as the veins of the arms or the abdomen.
- All or part of a DVT can break loose, and travel from the leg to the lung, blocking normal blood flow. This is known as a pulmonary embolism.



Who is at Risk?

Patients at risk include:

- Patients undergoing surgery
- Cancer patients with existing symptomatic blood clots
- Patients with restricted mobility due to acute illness

Other Risk Factors

Some of the risk factors that can contribute to a blood clot are:

- Being overweight
- Older age
- Cigarette smoking



What are the Symptoms?

DVT

Not everyone with DVT will experience symptoms. When symptoms are present they may include:

- Swelling of the leg or arm
- Pain or tenderness. Pain may only be experienced when touching the affected area or when standing or walking.
- Redness in the affected area



If you experience any of the symptoms of DVT, contact your doctor immediately.

About FRAGMIN

What is FRAGMIN used for?

FRAGMIN is used to:

- prevent blood clotting when surgery is performed **OR**
- treat the acute formation of blood clots in deep veins **OR**
- treat symptomatic blood clots to prevent recurrence of the clots in patients with cancer **OR**
- treat unstable coronary artery disease **OR**
- prevent clotting in those at risk when mobility is restricted during acute illness **OR**
- prevent clotting in blood dialysis and filtration equipment in connection with acute kidney failure or chronic kidney disease

What it does:

FRAGMIN is a type of medicine called low molecular weight heparin. FRAGMIN can help:

- keep the blood from forming clots **OR**
- keep a clot from getting larger

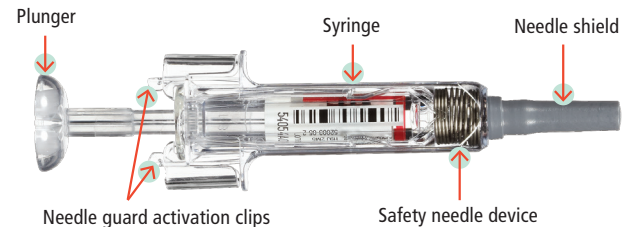
BEFORE YOUR RELEASE FROM THE HOSPITAL, YOUR HEALTHCARE PROFESSIONAL WILL SHOW YOU HOW TO GIVE YOURSELF THE FRAGMIN INJECTIONS.

IT IS VERY IMPORTANT THAT YOU FOLLOW THE INSTRUCTIONS EXACTLY.

IF THERE IS ANYTHING YOU DON'T UNDERSTAND OR WOULD LIKE CLARIFIED, MAKE SURE TO ASK YOUR HEALTHCARE PROFESSIONAL FOR MORE INFORMATION SO THAT WHEN YOU GO HOME, YOU ARE COMFORTABLE SELF-ADMINISTERING FRAGMIN.

FRAGMIN comes in both prefilled syringes with a safety needle device and multi-dose vials. Your healthcare professional will recommend the format that is suitable for you.

FRAGMIN PREFILLED SYRINGE WITH SAFETY NEEDLE DEVICE



FRAGMIN is given as a subcutaneous injection just under the skin. **FRAGMIN should NOT be administered intramuscularly.**

The rubber needle shield may contain latex. Talk to your doctor or pharmacist if you have had or currently have a hypersensitivity to latex (natural rubber).

Injection Instructions Using the FRAGMIN Prefilled Syringe with Safety Needle Device

You will need:

- ✓ An alcohol swab
- ✓ A FRAGMIN Prefilled Syringe with Safety Needle Device
- ✓ A cotton ball
- ✓ An approved container for used syringes



DO NOT attempt to remove the syringe from the blister packaging with your fingers.

Follow directions for correct handling technique as shown in steps 1 to 3, otherwise, the needle's safety mechanism may be triggered, making the syringe unusable.

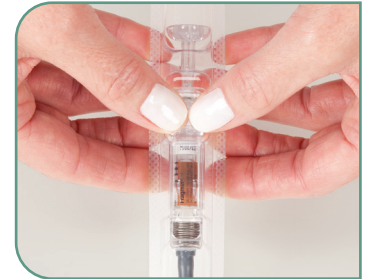
STEP 1

Peel off paper backing completely from the blister packaging.



STEP 2

Rotate the packaging so that the open side is facing downward between three to five centimetres above a flat surface, such as a table.



STEP 3

In order to release the syringe, pull apart the sides in the middle of the blister packaging to widen the blister cavity. This should cause the syringe to fall out of the blister.



STEP 4

Wash your hands.

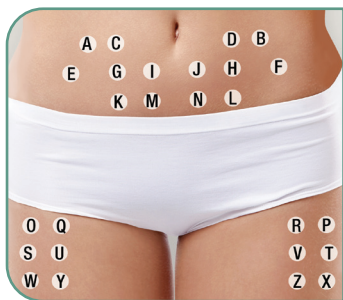


STEP 5

Choose the injection site.

The preferred site of injection is the lower abdomen.

FRAGMIN may also be injected into the side of the thigh, provided care is taken not to inject into the muscle tissue. Select a different site on the abdomen or thigh for each subsequent injection **as illustrated**.



STEP 6

Cleanse the site.

Wipe the area selected for injection with an alcohol swab and allow it to dry.



STEP 7

Pick up the syringe by the body and prepare to inject the FRAGMIN dose.

DO NOT touch the needle guard activation clips at any time during use. This may trigger the needle's safety mechanism causing the needle to retract (pull back) before your injection is given. This will make the syringe unusable.



STEP 8

Remove the needle shield.

Please note that a firm pull is needed to remove the needle shield. To ensure delivery of the full dose, **do not remove any small air bubbles from the prefilled syringe before injection.**



STEP 9

Pinch a fold of skin.

The needle must be inserted into the skin fold created with the thumb and forefinger.

This skin fold must be maintained throughout the injection.



STEP 10

Administer FRAGMIN.

Using your dominant hand, hold the syringe like a pencil between your thumb and middle finger. Insert the needle vertically into the skin fold as far as it will go. Once inserted, the needle should not be moved.



If you are self-injecting, depress the plunger using the forefinger; **if you are injecting someone else**, use the thumb to depress the plunger.

STEP 11

Remove the needle and activate the needle guard.

When you have injected all the contents of the syringe, remove the needle **while maintaining the skin fold and holding the plunger down, then release the skin.**



Let go of the plunger and allow the syringe to move up inside the device until the entire needle is guarded. **The needle guard will not be activated until the entire dose has been administered.**

STEP 12

After FRAGMIN has been administered. Press a cotton ball on the injection site for 5-10 seconds or longer. To avoid bruising, do not rub the injection site.



Discard the used syringe in an approved container. Ensure it is kept out of reach of children.

Medication Record for FRAGMIN

It is important that you record your medication use daily by filling out the table below.

Date	Dose	Injection Site	Notes

Your healthcare professional will use this information to make sure that you are taking FRAGMIN as prescribed. Bring this booklet with you every time you see your healthcare professional.



It is important that you follow the instructions of your healthcare professional carefully.

Give yourself the injections as prescribed **for the entire time period** specified by your doctor **and at the same time each day**.

Certain medications may intensify the anticoagulant effect of FRAGMIN.

Therefore it is important for you to advise your healthcare professional of all drugs, including non-prescription and herbal products, you are presently taking.

If you see another doctor or see your dentist, let them know you are taking FRAGMIN. This is especially important if you are going to have any operative procedures done (i.e., dental extractions, surgical procedures).

What Side Effects Should I Report to My Healthcare Professional?

The most common side effects are pain and bruising at the injection site. The most important side effect of anticoagulant drug therapy is bleeding.

Stop taking your medication and call your doctor or pharmacist if:

- There is bleeding at the injection site and/or the surgical site (a drop of blood at the injection site is normal)
- There is other bleeding: nosebleed, blood in urine, bleeding from the mouth, vagina, anus
- Your gums bleed while brushing your teeth
- You see purplish or reddish discoloration or notice pain and bruising around the injection site, if severe
- You have allergic reactions
- You experience easy bruising or bruising without apparent cause

Administration of FRAGMIN may result in bleeding which can have serious or life-threatening consequences. Hemorrhagic strokes (bleeding inside the brain) have been reported, but are rare. Serious intra-abdominal bleeding (bleeding inside the abdomen) has also been reported, but is uncommon.

Please consult the “Information for the Patient” leaflet included in the product package for complete information regarding precautions and adverse events.

What About Pregnancy?

If you are pregnant, breastfeeding or planning to become pregnant, you should discuss this promptly with your doctor so that the possible risks to you and your child can be assessed.

Because benzyl alcohol may cross the placenta, FRAGMIN 25 000 IU 3.8 mL multi-dose vials which are preserved with benzyl alcohol should not be used in pregnant women.

FRAGMIN

Safety Information

When FRAGMIN should not be used. If you have had or currently suffer from any of the following conditions, it is necessary that you inform your doctor before starting treatment: allergy to FRAGMIN or any of its ingredients or container (including benzyl alcohol when using the 25,000 IU multi-dose vial) or to other low molecular weight heparins and/or heparin or pork products; bleeding due to acute gastroduodenal ulcer (stomach or intestinal bleed/ulcer); a history of cerebral hemorrhage (bleeding in or against the brain); a severe blood clotting disorder (hemorrhagic diathesis); A history of confirmed or suspected low platelet count (thrombocytopenia) due to heparin, or a positive antiplatelet antibody test in the presence of Fragmin or other heparin or low molecular weight heparin products; bacterial infection of the heart (septic endocarditis); severe uncontrolled high blood pressure; disorders of the retina of the eye due to diabetes or bleeding; injuries to and/or operations on the central nervous system, eyes or ears; or any other diseases that could involve an increased risk of bleeding. Spinal or epidural anesthesia should not be used while receiving repeated high doses of Fragmin.

Because benzyl alcohol may cross the placenta, FRAGMIN 25 000 IU 3.8 mL multi-dose vials, which are preserved with benzyl alcohol, should not be used in pregnant women. Benzyl alcohol preparations should be used with caution in pediatric patients.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Fragmin. Talk about any health conditions or problems you may have, including if you: have artificial heart valves; have heart disease, including angina and recent heart attack; are taking any medications (such as

acetylsalicylic acid [ASA, aspirin], other drugs to reduce blood clotting such as warfarin or non-steroidal anti-inflammatory drugs [NSAIDS] to treat painful and/or inflammatory conditions of muscles or joints), including those that you buy without a prescription; bleeding disorders (such as hemophilia); have liver or kidney problems; have diabetes, metabolic acidosis, increased potassium, or taking potassium sparing drugs, due to the risk for high levels of potassium; are allergic to latex (natural rubber); Are at higher risk of bleeding (including elderly patients, patients with kidney problems or who are underweight or overweight or children); If you are pregnant or breast feeding.

Certain medications may intensify the anticoagulant effect (e.g., blood thinning effect) of FRAGMIN. Therefore, it is important for you to advise your doctor of any medications you may be taking.

Follow the instructions of your healthcare professional carefully. Give yourself the injections prescribed for the entire time period specified by your healthcare professional. Do not take any drugs other than those prescribed by your healthcare professional while you are taking FRAGMIN. FRAGMIN is administered as an injection underneath the surface of the skin (subcutaneously) and should not be administered intramuscularly. If you need to consult with another doctor or see your dentist, tell them that you are being treated with FRAGMIN.

FRAGMIN should be inspected visually for clarity, particulate matter, precipitation, discolouration and leakage prior to administration. Do not use product if mixture (solution) shows haziness, particulate matter, discolouration or leakage. Store your prefilled syringes at room temperature (15-30°C).

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Kirkland, Quebec H9J 2M5

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