



A guide for **patients with cancer** and symptomatic blood clots

**Treating your blood clots with FRAGMIN
to prevent a recurrence**

Pr **Fragmin**[®]
dalteparin sodium

Visit www.Fragmin.ca to find other helpful FRAGMIN resources such as a video on how to inject and printable injection instructions in 19 languages:

- English
- French
- Arabic
- Cantonese
- Cree
- Farsi
- Greek
- Hindi
- Italian
- Korean
- Mandarin
- Polish
- Portuguese
- Punjabi
- Serbian
- Spanish
- Tagalog
- Tamil
- Urdu

Use this number to enter the website:
02352664

Table of Contents

- 2 What Is a Blood Clot?
- 3 What Are Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)?
- 4 What Are the Symptoms of DVT?
- 5 What Are the Symptoms of PE?
- 6 Cancer and Venous Thromboembolism (VTE)
- 7 What Is FRAGMIN and How Does It Work?
- 7 Interactions with FRAGMIN
- 8 My FRAGMIN Treatment
- 9 FRAGMIN Dosage and Weight Chart
- 11 FRAGMIN at Home
- 12 Injection Instructions Using the FRAGMIN Prefilled Syringe with Safety Needle Device
- 18 FRAGMIN Safety Information

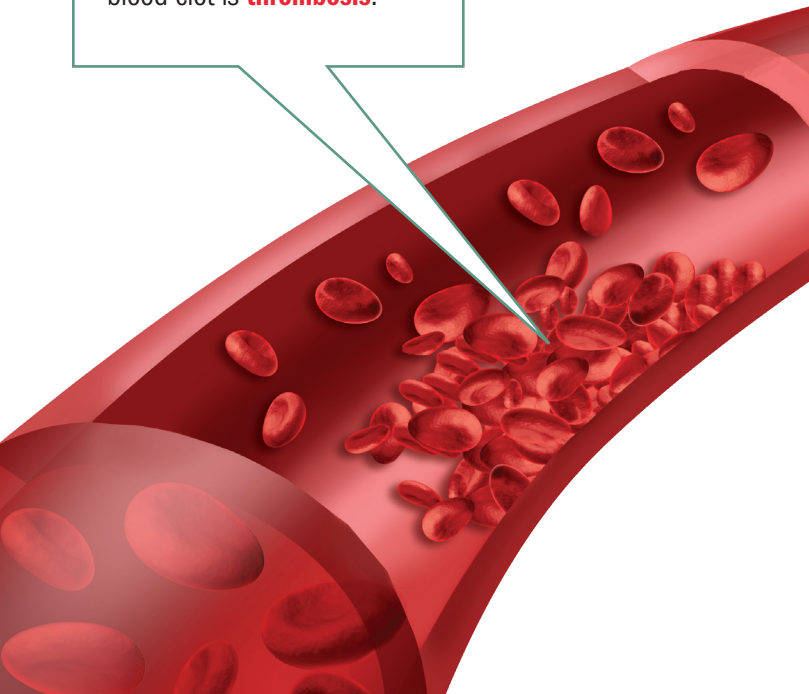


Use this booklet to help you understand why it is important for you to stay on FRAGMIN as prescribed.

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.

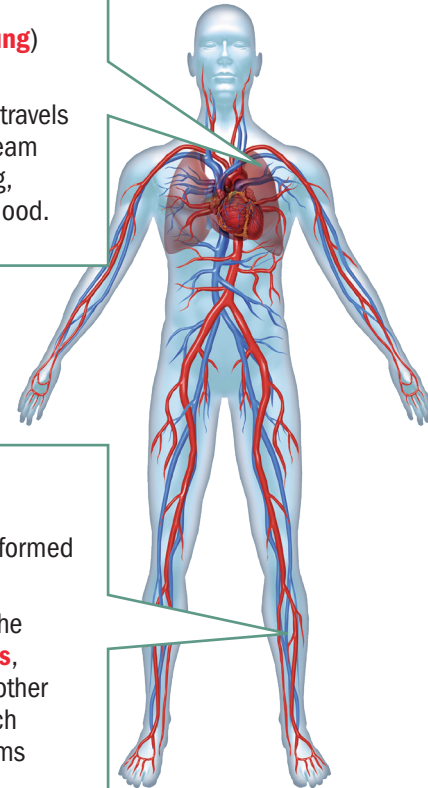
Sometimes, clots form abnormally within a blood vessel. The medical term for the development of an abnormal blood clot is **thrombosis**.



What Are Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)?

PE

- A blood clot in the pulmonary vessels (**lung**)
- A PE occurs when a blood clot breaks off, travels through the blood stream and lodges in the lung, blocking the flow of blood.



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 abdomen.

What Are the Symptoms of a DVT?



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

- Swelling of the leg or arm (may occur suddenly)
- Pain or tenderness in the leg that may only be present when standing or walking
- Feeling of increased warmth in the area of the leg or arm that is swollen or that hurts
- Redness or discolouration of the skin

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

What Are the Symptoms of a PE?



Symptoms of a PE include:

- Sudden, sharp chest pain
- Shortness of breath
- Chest pain that gets worse with deep breathing or coughing
- Coughing up blood or pink, foamy mucus
- Rapid heart rate
- Excessive sweating

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

Cancer and Venous Thromboembolism (VTE)

Venous thromboembolism (VTE) includes both **deep vein thrombosis (DVT)** and/or **pulmonary embolism (PE)**.

- VTE is one of the most common complications seen in patients with cancer.
- Patients with cancer are at least 6 times more likely to develop VTE compared with patients without cancer.

Why are patients with cancer at increased risk of developing VTE?

There are several reasons why patients with cancer are at increased risk of developing VTE:

- Some cancers produce substances that activate the clotting system
- Some cancer therapies can increase clotting risk
 - Certain chemotherapies, hormonal therapies and other drug therapies
 - Surgery
 - Radiation
- Catheters in the big veins can irritate the blood vessel and decrease blood flow

Talk to your doctor to fully understand your personal risk factors.

What Is FRAGMIN and How Does It Work?

FRAGMIN is a type of medicine called low molecular weight heparin. It can help keep the blood from forming clots or keep a clot from getting larger.

FRAGMIN works by making thrombin inactive in the body. Thrombin is an ingredient which contributes to blood clotting.

Interactions with FRAGMIN

Certain medications may intensify the anticoagulant effect of FRAGMIN. Therefore, it is important for you to advise your doctor if you are taking any medications such as:

- Acetylsalicylic acid (ASA)
- Other drugs to reduce blood clotting such as warfarin or non-steroidal anti-inflammatory drugs (NSAIDs; drugs used to treat painful and/or inflammatory conditions of muscles or joints)
- Platelet inhibitors
- Medication that you buy without a prescription

Make a list of **all** medications you are taking and be sure to let your doctors know about any changes.

My medications

My FRAGMIN Treatment

FRAGMIN is used for the extended treatment of symptomatic venous thromboembolism (VTE) to prevent recurrence of VTE in patients with cancer.

VTE associated with cancer is a serious condition. Your healthcare professional has prescribed FRAGMIN to treat your blood clot and to prevent a blood clot from coming back.

FRAGMIN should be used once a day for an extended treatment period of up to six months.

The treatment period with FRAGMIN will vary from patient to patient. Your healthcare professional will determine the length of time that is appropriate for you.

You have been prescribed
FRAGMIN for at least

enter
of

months

Fill in the information below to remind you of when you started FRAGMIN.

Date I **started**
FRAGMIN treatment:

enter date

If you miss a dose, tell your healthcare professional.

Do not take two doses at the next dosage time.

Make sure you renew your prescription each month and ensure that you complete your treatment with FRAGMIN.

FRAGMIN Dosage and Weight Chart

FRAGMIN is supplied in a number of different doses. Based on your body weight, your healthcare professional will determine which dose is appropriate for you.

FRAGMIN Dose at Initial Visit: _____

New FRAGMIN Dose: _____

Should you lose or gain weight, advise your healthcare professional, as the dosage of FRAGMIN may need to be adjusted.

Keep track of your weight and show this booklet at each visit.

Weight at Initial Visit: _____

Weight: _____ Date: _____

Weight: _____ Date: _____

Weight: _____ Date: _____

It's important to stay on FRAGMIN as prescribed by your healthcare professional to help prevent another blood clot from forming.



FRAGMIN at Home

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

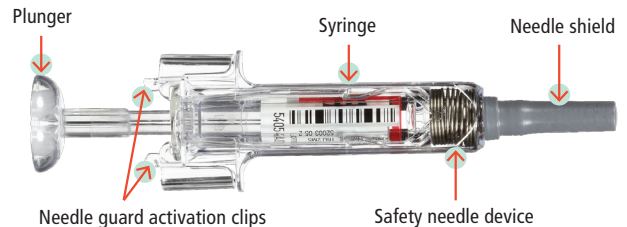
Do not use product if mixture (solution) shows haziness, particulate matter, discolouration or leakage.

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, BE SURE TO ASK YOUR HEALTHCARE PROFESSIONAL FOR MORE INFORMATION SO THAT WHEN YOU GO HOME, YOU ARE COMFORTABLE SELF-ADMINISTERING FRAGMIN.

FRAGMIN PREFILLED SYRINGE WITH SAFETY NEEDLE DEVICE



For instructions to help you safely inject FRAGMIN using:

Prefilled Syringe with Safety Needle Device: see page 12.

Multi-Dose Vial: please consult the Fragmin.ca website.

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 when removing the prefilled syringe with safety needle device from the packaging, 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

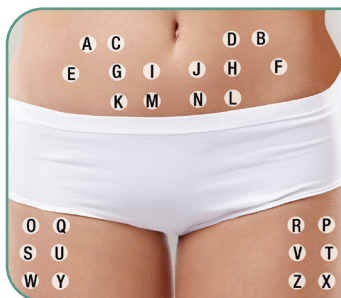
Wash your hands.



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.



FRAGMIN

Safety Information

FRAGMIN (dalteparin sodium injection) is used to treat symptomatic blood clots to prevent recurrence of the clots in patients with cancer.

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 constituents or to other low molecular weight heparins and/or heparin; 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 thrombocytopenia (decrease in the number of platelets); bacterial infection of the heart (septic endocarditis); 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.

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.

BEFORE you use FRAGMIN, talk to your doctor or pharmacist if you have had or currently have: artificial heart valves; heart disease, including angina and recent heart attack; if you are taking any medications (such as acetylsalicylic acid [ASA], 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; liver or kidney problems; hypersensitivity to latex (natural rubber). If you are pregnant or breastfeeding, tell your doctor so that the possible risks to you and your child can be assessed.

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 doctor or nurse carefully. Give yourself the injections prescribed for the entire time period specified by your doctor. Do not take any drugs other than those prescribed by your doctor 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°C–30°C).

The most common side effects are pain and bruising at the injection site. Talk to your doctor or pharmacist if you experience purplish or reddish discolouration or pain, and bruising around the injection site.

Stop taking FRAGMIN and contact your doctor if you experience: severe discolouration, pain or bruising around the injection site; bruising without apparent cause; nosebleed; bleeding from the mouth, gums, abdomen, anus or vagina; bleeding at the injection site or from a surgical site; allergic reactions; blood in the urine; or if you experience a stroke (bleeding inside the brain). For any unexpected effects while taking FRAGMIN, contact your doctor or pharmacist immediately.

[illegible][illegible]

FRAGMIN ® Pfizer Health AB, owner/
Pfizer Canada ULC, Licensee

® Pfizer Inc., used under license

© 2021, Pfizer Canada ULC,
Kirkland, Quebec H9J 2M5

PP-FRA-CAN-0269-EN

