

FRAGMIN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or nurse.

1. Why am I being treated with FRAGMIN?

FRAGMIN contains the active ingredient dalteparin sodium, derived from pig intestines. It is used to treat and/or prevent blood clots forming in deep blood vessels and/or your lungs (in patients with some cancers); treat certain types of heart disease; prevent clots before and after an operation or during kidney dialysis. For more information, see Section [1. Why am I being given FRAGMIN?](#) in the full CMI.

2. What should I know before being treated with FRAGMIN?

Do not start treatment if you have ever had an allergic reaction to dalteparin sodium/heparin/other medicines derived from heparin, pork products, or any of the ingredients listed at the end of the CMI; have major bleeding disorders; injury to the brain including stroke;

stomach/bowel problems; bacterial infections in your heart/heart valves; very high blood pressure; or following injury or operation on your brain, spinal cord, eyes or ears.

Talk to your doctor if you have: allergy to latex (natural rubber); medical conditions which involve increased risk of bleeding including stomach ulcers or blood clotting disorders; high blood pressure; heart infections or an artificial heart valve; diabetes or eye disease related to diabetes; kidney or liver disease; cancer including brain tumours; had recent surgical procedures; had metabolic acidosis or high blood potassium; are being treated for severe pain; take any medicines; or are pregnant, planning to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before being given FRAGMIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FRAGMIN and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is FRAGMIN given?

FRAGMIN is given by injection either under the skin, or as a slow 'drip' into a vein. If you need to use FRAGMIN after you have left hospital, you will be taught to self-inject. More instructions can be found in Section [4. How is FRAGMIN given?](#) in the full CMI.

5. What should I know during treatment with FRAGMIN?

Things you should do	<ul style="list-style-type: none">• If you need to have any medical, dental or surgical procedures, tell your doctor, dentist, anaesthetist or pharmacist that you are/have recently been treated with FRAGMIN• Tell your doctor if you have any unusual bruising or bleeding; back pain, numbness or weakness
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	<p>in limbs, problems going to the toilet; chest pain or unusual heartbeats</p> <ul style="list-style-type: none"> • Tell your doctor if you become pregnant while being treated with FRAGMIN
Things you should not do	<ul style="list-style-type: none"> • Do not stop taking this medicine or change the dosage without checking with your doctor. • Do not inject FRAGMIN into a muscle.
Driving or using machines	<ul style="list-style-type: none"> • FRAGMIN does not affect the

	<p>ability to drive or operate machinery. Be careful driving or operating machinery until you know if FRAGMIN affects you.</p>
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Keep the prefilled syringes in their pack until you are ready to use them in a cool, dry place where the temperature stays below 25 degrees Celsius (FRAGMIN 10,000 IU) or below 30 degrees Celsius (FRAGMIN

	2,500 IU, 5,000 IU, 12,500 IU, 15,000 IU & 18,000 IU).
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For more information, see Section [5. What should I know during treatment with FRAGMIN?](#) in the full CMI.

6. Are there any side effects?

Side effects may include: allergic reaction; pain/bruising/lump at injection site; hair loss; unusual bleeding including nosebleeds, blood in wee/poo; tingling/numbness of hands/feet or limbs; slow/irregular heartbeat; dizziness; fever; muscle weakness; severe headache; bleeding on the brain; osteoporosis; rash, blisters; upset stomach/pain/vomiting; chest pain; fainting; tiredness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FRAGMIN® ('frahg-minh')

Active ingredient(s): *Dalteparin sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about being treated with FRAGMIN. **You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about being treated with FRAGMIN.**

Where to find information in this leaflet:

- [1. Why am I being treated with FRAGMIN?](#)
- [2. What should I know before being treated with FRAGMIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is FRAGMIN given?](#)
- [5. What should I know during treatment with FRAGMIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with FRAGMIN?

FRAGMIN belongs to a group of medicines known as low molecular weight heparins (LMWHs). It contains the active ingredient dalteparin sodium, which is derived from pig intestines.

FRAGMIN is used to treat:

- Deep vein thrombosis, "DVT" (a blood clot in a deep vein, usually in the leg or arm)
- Blood clots in the veins of the lungs (pulmonary embolism), in certain types of cancer
- Unstable heart disease caused by poor blood flow in the blood vessels of the heart (e.g. angina or heart attack).

FRAGMIN may also be used to prevent:

- DVTs before or after an operation
- Blood clotting during haemodialysis, a procedure that uses a machine to remove waste products from the blood in people with kidney failure.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

2. What should I know before being treated with FRAGMIN?

Warnings

You should not be given FRAGMIN:

- If you have an allergy to dalteparin sodium, heparin or other similar medicines (such as other LMWHs), pork products, or any of the ingredients listed at the end of this leaflet.

- always check the ingredients to make sure you can be given this medicine.
- if you have, or have ever had, any of the following medical conditions: major bleeding disorders (e.g. haemophilia, severe liver disease); certain types of injury to the brain including stroke (bleeding in your brain); stomach or bowel problems, such as ulcers or ulcerative colitis; bacterial infections in your heart or heart valves; very high blood pressure.
- following an injury or operation on your brain, spinal cord, eyes or ears.

If you are being treated with FRAGMIN, you should not:

- have a procedure known as 'sympathetic block' (where anaesthesia medicine is injected to treat specific types of pain).

If you are being treated with high doses of FRAGMIN (eg. for blood clots in the lung or poor blood flow in the heart), you should not:

- have a procedure known as 'regional anaesthesia' (where only a specific area of the body is numbed, so you can stay awake or sedated while undergoing a procedure or surgery without losing consciousness).

Check with your doctor if you:

- have an allergy to latex (natural rubber). The needle shield on the pre-filled syringe may contain latex.
- have any other medical conditions such as: low platelet count (thrombocytopenia); high blood pressure; severe problems with blood clotting,

bleeding or bruising; infection or inflammation of the heart valves or have an artificial heart valve; diabetes; eye disease related to diabetes or high blood pressure; kidney or liver disease, cancer including brain tumours or thinning of the bones (osteoporosis).

- take any medicines for any other condition including other anticoagulant/antiplatelet medicines or chemotherapy treatment.
- have had any recent surgical procedures.
- have ever had metabolic acidosis (a serious electrolyte disorder) or high potassium in your blood.

If your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection), tell your doctor you are being treated with FRAGMIN.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant, intend to become pregnant or are breastfeeding.

FRAGMIN is not recommended for use during pregnancy as it may result in adverse outcomes for the pregnant woman or unborn child. Discuss the risks with your doctor.

FRAGMIN is not recommended for use during breastfeeding. FRAGMIN may pass into breastmilk.

Use in children

- It is not recommended that FRAGMIN be given to children.

Use in the elderly

- FRAGMIN should be used with caution in the elderly, especially in patients aged 80 years and above, as they may be at an increased risk of bleeding complications, even when the correct dosages are being used.

3. What if I am taking other medicines?

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

Some medicines may interfere with FRAGMIN and affect how it works.

Medicines that may increase the effect of FRAGMIN (i.e. increase the risk of bleeding) include:

- Non-steroidal anti-inflammatory drugs ('NSAIDs') - such as naproxen, ibuprofen, diclofenac, piroxicam, meloxicam, indometacin and keterolac
- Aspirin, however this may be prescribed by your doctor to take with FRAGMIN. Speak with your doctor before taking aspirin.

- Anticoagulants ('blood thinners') - such as warfarin, heparin and other medicines derived from heparin eg. enoxaparin sodium
- Platelet inhibitors - such as clopidogrel, prasugrel, ticagrelor, tirofiban, eptifibatide and dipyridamol
- Thrombolytics (clot-dissolving medicines) - such as alteplase, tenecteplase, apixaban, rivaroxaban and dabigatran
- Dextran, a medicine used to treat shock, which occurs when you have dangerously low blood pressure
- probenecid, a medicine used to treat gout, certain complications associated with HIV, or used in conjunction with certain antibiotic treatment
- medicines used to treat some cancers (known as 'cytostatics' - cytarabine, daunorubicin, fluorouracil and methotrexate are some examples)

Medicines that may decrease the effect of FRAGMIN (i.e. increase the risk of clotting) include:

- medicines to control bleeding such as andexanet alfa
- antihistamines (medicines used to prevent or relieve the symptoms of allergy, hay fever or rashes) - especially those containing diphenhydramine
- digoxin, a medicine used to treat heart failure
- tetracycline antibiotics, such as doxycycline, minocycline and tigecycline
- medicines or vitamins that contain ascorbic acid (vitamin C).

FRAGMIN may also increase blood potassium levels in patients taking the following medicines:

- potassium salts, some fluid tablets (e.g. amiloride, spironolactone and eplerenone), some medicines for heart problems (e.g. perindopril, lisinopril, enalapril and telmisartan, candesartan, irbesartan, losartan) and some antibiotics (e.g. trimethoprim and pentamidine).

If you are taking any of these medicines while using FRAGMIN, your doctor will need to carefully monitor your blood clotting factors and other blood levels, such as potassium.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FRAGMIN.

4. How is FRAGMIN given?

How much is given

Your doctor will decide what dose, how often and how long you will receive FRAGMIN. This depends on your condition and other factors, such as your age, weight, level of mobility, how well your kidneys are working, and whether other medicines are being given at the same time.

If you are being treated for deep vein thrombosis (DVT), your doctor may tell you to start taking another oral medicine to prevent blood clots, such as warfarin tablets.

If you are being treated for unstable heart disease (e.g. angina or heart attack), your doctor might tell you to take aspirin as well.

How it is given

- FRAGMIN may be given as an injection either under the skin (subcutaneously) or through a slow infusion “drip” into a vein (intravenously).
- It should not be given as an injection into a muscle (intramuscularly).
- FRAGMIN is usually only given by a doctor or nurse. However, in certain conditions you might have to use FRAGMIN after you have left hospital. In that case, your doctor or nurse will teach you how to self-inject before you leave the hospital.

How to use FRAGMIN at home

To inject FRAGMIN, you should be sitting or lying down.

Do not expel the air bubble from the syringe before injection. This should ensure delivery of the full dose.

The injection should be given under the skin. You can inject yourself in either your stomach or the fleshiest part of your upper buttock.

Your doctor or nurse will tell you which of these two areas is better for you to use. Whichever area you use, try to make sure that you inject yourself in slightly different spots each time to avoid soreness at the injection site.

Before you inject, make sure that the injection site is clean by wiping the area with an antiseptic or alcohol swab, or by washing it with soap and water and patting it dry with a clean towel.

If you are injecting yourself in the stomach, you will need to lift up a fold of skin to make a slight bulge, as the layer of fat may be quite thin. Keep a firm grip of the skin throughout the whole injection without pinching yourself too tightly.

If you are injecting yourself in the buttock, there is no need to lift a fold of skin, as the layer of fat is thick enough.

Hold the base of the rubber cover that protects the needle, then twist to remove it from the needle. Insert the needle into the skin vertically, as far as it will go. Press on the plunger and withdraw the needle when you have injected the whole content of the syringe.

Dispose of the used syringe and needle in a safe manner. If you have any questions, ask your doctor or nurse for help.

If you forget to use FRAGMIN

IF YOU HAVE TWICE DAILY INJECTIONS:

If it is less than 6 hours since you should have injected, give yourself an injection and then continue as usual. If more than 6 hours has passed, give yourself the next injection when it is time to do so.

IF YOU HAVE ONCE DAILY INJECTIONS:

If it is less than 12 hours since you should have injected, give yourself an injection as soon as you can and then continue as usual. If more than 12 hours have passed, give yourself the next injection when it is time to do so.

In either case, contact your doctor if you are concerned or have any questions.

If you are given too much FRAGMIN

If FRAGMIN is being given to you in hospital, it is given under the close supervision of your doctor, so it is very unlikely that you will receive too much. Your condition will also be carefully monitored following administration. A symptom of too much FRAGMIN may be abnormal bleeding.

Tell your doctor or nurse immediately if you are concerned that you may have been given too much FRAGMIN.

If you are using FRAGMIN at home and you think that you have used too much, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with FRAGMIN?

Things you should do

Use FRAGMIN exactly as your doctor has prescribed.

Remind any doctor, dentist or pharmacist you visit that you are using FRAGMIN.

If you are going to have surgery or undergo any procedures involving anaesthesia medicines (including spinal or epidural injections), tell your doctor, anaesthetist or dentist that you are being treated with FRAGMIN.

FRAGMIN may affect other medicines used during those procedures.

Follow your doctor's instructions carefully and be sure to keep all medical appointments.

Your doctor may ask you to have blood tests to check your progress and prevent unwanted side effects, particularly if you have cancer, liver or kidney disease or are very thin or very overweight.

Tell your doctor straight away if you:

- become pregnant while using FRAGMIN. FRAGMIN is not recommended for use during pregnancy.
- experience back pain, numbness or weakness in your lower limbs or have any problems going to the toilet.

- experience any unusual bruising or abnormal bleeding.
- have chest pain, fast or irregular heartbeat, or muscle weakness or numbness in your limbs.

Things you should not do

- Do not use FRAGMIN to treat any other complaints unless your doctor tells you to.
- Do not give FRAGMIN to anyone else, even if they have the same condition as you.
- Do not stop using your medicine or change the dosage without checking with your doctor.
- Do not mix FRAGMIN with other injections or infusion solutions.
- Do not inject FRAGMIN into a muscle.

FRAGMIN is not interchangeable with other low molecular weight heparins (LMWHs), such as exoxaparin sodium, or other heparin products.

Driving or using machines

Be careful driving or operating machinery until you know if FRAGMIN affects you.

Drinking alcohol

No information is available. If you drink alcohol discuss this with your doctor while using FRAGMIN.

Looking after your medicine

In the hospital, FRAGMIN will be stored in the pharmacy or on the ward under the correct conditions.

If using FRAGMIN at home, follow the instructions in the carton on how to take care of your medicine properly.

Keep the syringes in the pack until it is time to use them. If you take the syringes out of the pack, they may not keep well.

Keep FRAGMIN in a cool dry place away from moisture, heat and sunlight, where the temperature stays below:

- 30 degrees Celsius for FRAGMIN 2,500 IU, 5,000 IU, 12,500 IU, 15,000 IU and 18,000 IU.
- 25 degrees Celsius for FRAGMIN 10,000 IU.

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Dispose of the used syringe and needle safely in a 'sharps' container or similar puncture proof container made of hard plastic.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or nurse if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• change in skin colour, a hard bruised lump, or pain or bruising at the injection site• hair loss• fever• rash, which may be itchy• fluid filled blisters on the skin• receding gums, brittle nails, weaker hand grip, back pain, stooping posture (which could be early signs of osteoporosis)	Speak to your doctor or nurse if you have any of these side effects and they worry you.

Side effects	What to do
<ul style="list-style-type: none"> • allergic reaction (rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing) • any bleeding, including from the site of an operation • more intense pain/ changes to skin colour around the injection site, or the skin starts to swell, gets warm/red, becomes numb or starts to blister • dizziness, extreme tiredness, muscle weakness, salt craving, upset stomach • easy bruising, red/purple spots on your skin, unusual bleeding such as nosebleeds, bleeding gums, prolonged bleeding from minor cuts, blood in your urine/ wee or black tarry poo 	<p>If you are already in hospital, alert your doctor or nurse straight away, if you notice any of these side effects.</p> <p>If you are being treated at home, call your doctor or go to your nearest hospital if you notice any of these serious side effects.</p>

Side effects	What to do
<ul style="list-style-type: none"> ● high blood potassium levels (muscle weakness, numbness or tingling in the arms and legs, feeling sick or vomiting, especially with difficulty breathing, chest pain and a slow or irregular heartbeat). ● severe back pain, weakness or numbness in your arms or legs, losing control of your bladder/wee or bowel/poo ● pain in your stomach, back, side or groin, especially if tender, swollen or bruised, especially with fast heart rate and pale skin ● severe headache combined with feeling sick, vomiting, dizziness and confusion, or difficulty speaking or seeing, weakness or numbness on one side of your body 	

Side effects	What to do
<ul style="list-style-type: none"> sudden shortness of breath, fainting and chest pain 	

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side-effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or nurse before you decide to stop taking any of your medicines.

7. Product details

What FRAGMIN contains

Active ingredient (main ingredient)	dalteparin sodium
Other ingredients	water for Injections

(inactive ingredients)	2,500 IU & 10,000 IU only: sodium chloride
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Do not take this medicine if you are allergic to any of these ingredients.

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

What FRAGMIN looks like

FRAGMIN is a clear, colourless or straw-coloured solution. The solution is contained in a pre-filled glass syringe.

A non-removable needle is attached to each syringe, which is enclosed by a needle shield.

FRAGMIN is available as fixed single dose syringes:

2,500 IU/0.2 mL: AUST R 25347

5,000 IU/0.2 mL: AUST R 25349

12,500 IU/0.5 mL: AUST R 61939

15,000 IU/0.6 mL: AUST R 61938

18,000 IU/0.72 mL: AUST R 61937.

It is also available as graduated single dose syringes:

10,000 IU/1 mL: AUST R 66626.

Who distributes FRAGMIN

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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