

FRAGMIN®

Dalteparin sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FRAGMIN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using FRAGMIN against the expected benefits it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again later.

What FRAGMIN is used for

FRAGMIN is used to prevent blood clots forming in blood vessels. It is used in the following conditions:

- treatment of deep vein thrombosis (also known as DVT, a blood clot in the veins of the leg)
- treatment of DVT and pulmonary embolism (blood clot in the veins of the lungs) for up to 6 months in patients with certain types of cancers
- prevention of DVT before and after an operation
- treatment of unstable heart disease (e.g. angina and heart attack), which is caused by poor blood flow in the blood vessels of the heart.

FRAGMIN is also used to prevent blood clotting during haemodialysis, a procedure that uses a machine to remove waste products from the blood in people with kidney failure.

FRAGMIN belongs to a group of medicines called low molecular weight heparins (LMWHs). These medicines work by reducing blood clotting activity.

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

Your doctor may have prescribed FRAGMIN for another reason.

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

Before you use FRAGMIN

When you must not use it

Do not use FRAGMIN if you have an allergy to:

- any medicine containing dalteparin sodium
- any other low molecular weight heparin or similar medicines such as heparin
- pork products
- 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 FRAGMIN if you have or ever had any of the following medical conditions:

- low platelet count caused by heparin
- stomach or bowel problems such as ulcers or ulcerative colitis
- a certain type of stroke caused by bleeding in the brain
- uncontrolled high blood pressure
- severe problems with blood clotting
- infection and inflammation of the heart valves.

Do not use FRAGMIN:

- following an injury or operation on your brain, spinal cord, eyes or ears
- if you are being treated for deep vein thrombosis (a blood clot in the veins of the leg), pulmonary embolism (blood clot that has travelled to the lungs) or unstable heart disease (e.g. angina and heart attack), and you are going to have surgery that requires a local anaesthetic
- if you will be given an anaesthetic injection in your back (spinal or epidural injection).

Do not use FRAGMIN after the expiry date printed on the pack.

Do not use FRAGMIN if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start treatment with

FRAGMIN, talk to your doctor or pharmacist.

FRAGMIN is not recommended for use in children, as its safety and effectiveness have not been established in children.

Before you start to use it

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

Tell your doctor if you have an allergy to latex (natural rubber). The needle shield on the pre-filled syringe may contain latex.

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

- eye disease related to diabetes or high blood pressure
- kidney or liver disease
- thinning of the bones (osteoporosis)
- problems with bleeding or bruising
- an artificial heart valve.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

FRAGMIN is not recommended for use during pregnancy or breastfeeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you start treatment with FRAGMIN.

Taking other medicines

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

Some medicines may alter the effects of FRAGMIN. These include:

- medicines or substances used to prevent or treat blood clots
- andexanet alfa, a medicine used to control bleeding
- Dextran, a medicine used to treat shock, which occurs when you

have dangerously low blood pressure

- aspirin and non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- probenecid, a medicine used to treat gout
- medicines used to treat some cancers
- ethacrynic acid, a medicine used to help the kidneys get rid of salt and water by increasing the amount of urine produced
- antihistamines, medicines used to prevent or relieve the symptoms of allergy, hay fever or rashes
- digoxin, a medicine used to treat heart failure
- tetracycline, an antibiotic used to treat some infections
- medicines that contain ascorbic acid (vitamin C).

If you are taking any of these medicines while using FRAGMIN, your doctor will need to carefully monitor your blood clotting factors.

These medicines may be affected by FRAGMIN or may affect how well it works. You may need to use different amounts of your medicine or you may need to use different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has a complete list of medicines to be careful with or avoid while using FRAGMIN.

Using FRAGMIN

How it is given

FRAGMIN is given by injection, either under the skin (subcutaneously) or into a vein (intravenously). The dose and length of treatment will depend on your condition. Your doctor or nurse will usually give you your injection.

If you are being treated for deep vein thrombosis, 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. unstable angina or heart attack, your doctor might tell you to take aspirin as well.

Using it at home

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.

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 is 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 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, twist to

remove 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 it

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.

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 use too much (overdose)

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

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers of these facilities handy.

While you are using FRAGMIN

Things you must do

Use FRAGMIN exactly as your doctor has prescribed.

If you are about to be started on any new medicine, remind your doctor, dentist and pharmacist that you are using FRAGMIN.

If you are going to have surgery, tell your doctor, anaesthetist or dentist that you are being treated with this medicine.

It may affect other medicines used during surgery.

Tell your doctor that you are using FRAGMIN if you are going to have a local anaesthetic or an anaesthetic injection in your back (spinal or epidural injection).

If you become pregnant while using FRAGMIN, tell your doctor immediately.

Things you must 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.

Things to be careful of

FRAGMIN is not interchangeable with other low molecular weight heparins (LMWHs) or heparin products.

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

Your doctor may ask you to have blood tests to prevent unwanted side effects.

Side effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well during or after treatment with FRAGMIN.

All medicines can have 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.

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 side effects and they worry you:

- pain and bruising at the injection site
- hair loss.

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

- low blood platelet count, which you may notice as unusual bleeding or bruising such as blood in the urine or bowel motions, black tarry bowel motions or black vomit
- symptoms of high potassium level in the blood, such as, nausea, fatigue, muscle weakness, tingling or numbness of the hands or feet, a slow or irregular heartbeat.
- allergic reactions, including rash, hives, itching, blisters, skin necrosis (black-purple skin), low blood pressure (dizziness or light-headedness) and fever
- back pain, tingling, numbness or weakness in your legs, which could mean bleeding around your spinal cord.

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

Tell your doctor, nurse or pharmacist immediately if you notice anything that is making you

feel unwell during or after treatment with FRAGMIN.

Other side effects not listed above may also occur in some patients.

Some of these side effects can be found only when your doctor does tests from time to time to check your progress. (e.g. changes in liver function shown in blood tests, increased blood potassium level).

After using FRAGMIN

Storage

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 where the temperature stays below:

- 30 degrees Celsius for FRAGMIN 2,500 IU and 5,000 IU
- 25 degrees Celsius for the other FRAGMIN products.

The recommended storage conditions for your product are shown on the carton.

Do not store FRAGMIN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Discard any unused solution.

A solution for infusion should be used within 12 hours of its preparation.

Keep FRAGMIN 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

Dispose of the used syringe and needle safely in a 'sharps' container or similar puncture

proof container made of hard plastic.

If your doctor tells you to stop using FRAGMIN or you find that the syringes have passed their expiry date, ask your doctor or pharmacist what to do with any that are left over.

Product description

What it 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.

FRAGMIN comes in five sizes of single fixed dose syringes and two sizes of graduated single dose syringes. The 7,500 IU and 10,000 IU graduated syringes have measurement markings to allow the dose to be adjusted.

Ingredients

FRAGMIN contains 2500, 5000, 10000, 12500, 15000 or 18000 IU of dalteparin sodium as the active ingredient. FRAGMIN also contains water for injections and sodium chloride (only 2500 IU and 10,000 IU).

Supplier

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

Australian registration numbers

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.

Graduated single dose syringes

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

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