New Zealand Consumer Medicine Information

Crusia-AFT® and Crusia-AFT® Forte*

Enoxaparin sodium 100 mg/mL and 150 mg/mL solution for injection

** Subsequent references to "Crusia-AFT" refer to both Crusia-AFT and Crusia-AFT Forte.*

What is in this leaflet

This leaflet answers some common questions about Crusia-AFT. 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 Crusia-AFT against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Crusia-AFT is used for

Crusia-AFT is used in a number of medical conditions. It is used to:

- treat blood clots
- treat certain types of heart disease (e.g. angina and heart attacks), when used with aspirin
- prevent blood clots forming after an operation, during hospitalisation or extended bed rest or during purification of the blood by an artificial kidney (haemodialysis).

Crusia-AFT is one of a group of medicines called low molecular weight heparins (LMWHs). These medicines work by reducing blood clotting activity.

Your doctor may have prescribed Crusia-AFT for another reason.

Ask your doctor if you have any questions about why Crusia-AFT has been prescribed for you.

There is no evidence that Crusia-AFT is addictive.

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

Before you are given Crusia-AFT

When you must not use it

Do not use Crusia-AFT if you have an allergy to Crusia-AFT, heparin or its derivatives including other LMWHs. Some signs and symptoms of an allergic reaction can include swelling of the face, lips or tongue, wheezing or troubled breathing, skin rash, itching hives, blisters or peeling skin.

Do not use Crusia-AFT if you have, or have ever had any of the following medical conditions:

- major blood disorders
- certain types of stroke
- stomach or bowel problems such as ulcers or ulcerative colitis
- bacterial infections in your heart
- immune-mediated heparin-induced thrombocytopenia (HIT), a condition associated with heparin treatment that results in a low platelet count and can cause blood clots.

Do not give Crusia-AFT to a child. The safety and effectiveness of Crusia-AFT have not been established in children.

Do not use Crusia-AFT after the expiry date printed on the syringe.

Do not use Crusia-AFT if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Crusia-AFT, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- heparin or its derivatives, including other LMWHs
- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

- major bleeding disorder or blood clotting problem, including a recent stroke or hereditary blood disorders
- bacterial endocarditis, inflammation of the lining of the heart caused by bacteria
- stomach or bowel problems such as ulcers or ulcerative colitis
- kidney or liver disease
- uncontrolled high blood pressure
- diabetic related eye disease
- recently undergone brain, spinal or eye surgery
- history of spinal surgery or spinal deformity
- an artificial heart valve

- low weight
- obesity

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Crusia-AFT.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. Like most LMWHs, Crusia-AFT is not recommended to be used during pregnancy. If there is a need to consider Crusia-AFT during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed. Like most LMWHs, Crusia-AFT is not recommended while you are breastfeeding. If there is a need to consider Crusia-AFT while you are breastfeeding, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Tell your doctor that you are using Crusia-AFT if your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Crusia-AFT.

Taking other medicines

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

Some medicines and Crusia-AFT may interfere with each other. These include:
- medicines or substances used to prevent and treat blood clots
- medicines containing aspirin or salicylates
- Dextran 40, a medicine use to treat shock
- medicines used to treat inflammatory disease, such as oral non-steroidal anti-inflammatory medicines or corticosteroids.
- anti-platelet medicines, including ticlopidine, clopidogrel, glycoprotein IIb/IIIa antagonists and systemic glucocorticoids.

If any of these medicines are used while using Crusia-AFT, careful monitoring of your blood clotting factors is required by your doctor.

These medicines may be affected by Crusia-AFT 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 and pharmacist may have more information on medicines to be careful with or avoid while using Crusia-AFT.

How to use Crusia-AFT

How much to use

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

For the prevention of blood clots, the following are the usual doses, which are administered by injection under the skin once a day:

- moderate risk patients: 20 mg
- high risk patients: 40 mg

For the treatment of blood clots which have formed in the leg/deep vein, the usual dose is 1 mg/kg body weight twice a day or 1.5 mg/kg body weight once a day injected under the skin. Warfarin sodium therapy is usually started within 72 hours of Crusia-AFT by your doctor.

For patients that require dialysis, the usual dose is 1 mg/kg into the tubing of the dialysis machine at the start of the session. Additional doses may be given if required.

For treatment of severe heart attacks, the usual dose is 30 mg injected into a vein plus 1 mg/kg injected under the skin, followed by 1 mg/kg injected under the skin twice a day.

For treatment of certain other types of heart disease, the usual dose is 1 mg/kg injected under the skin twice a day.

These doses of Crusia-AFT may be changed by your doctor. Your doctor will decide when and how much Crusia-AFT you will be given.

How to use it

Crusia-AFT is usually given by an injection under the skin or into the tubing of the dialysis machine. The recommended site for injection is the stomach area. A different injection site should be used for each injection. Do not rub the injection site after administration.
It may be given by your doctor, nurse or yourself. Your doctor will tell you how you will be given your injection.

Crusia-AFT can also be given by an injection into a vein. This will be done in hospital by your doctor or nurse.

Prefilled syringes
The prefilled syringes are ready for use. The air bubble in the syringe should not be expelled.

Graduated prefilled syringes
When using the 60 mg, 80 mg, 100 mg, 120 mg and 150 mg graduated syringes, the volume to be injected should be measured precisely according to the dosage recommended by your doctor.

Injection technique
The whole length of the syringe needle should be introduced vertically into the thickness of a skin fold gently held between the operator's thumb and finger. This skin fold should be held throughout the duration of the injection.

Crusia-AFT does not contain any antimicrobial agents, so must be used once only and any residue discarded.

How long to use it

Your doctor will tell you how long you will be using Crusia-AFT.

While you are using Crusia-AFT

Things you must do

Use Crusia-AFT exactly as your doctor has prescribed.

If you become pregnant while using Crusia-AFT tell your doctor immediately.

Tell your doctor if you have an artificial heart valve.

If you are about to be started on any new medicine tell your doctor, dentist or pharmacist that you are using Crusia-AFT.

Tell any other doctors, dentists or pharmacists who are treating you that you are using Crusia-AFT.

If you plan to have surgery, tell your doctor or dentist that you are using Crusia-AFT.

Tell your doctor that you are using Crusia-AFT if your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).

Things you must not do

Do not give Crusia-AFT to anyone else, even if they have the same condition as you.

Do not use Crusia-AFT to treat any other complaints, unless your doctor tells you to.

Do not stop using Crusia-AFT, or lower the dosage, without checking with your doctor or pharmacist.

Do not mix Crusia-AFT with other injections or infusion fluids. Certain medicines or solutions contain ingredients that can interact with Crusia-AFT. If you need an injection of Crusia-AFT into a vein, your doctor or nurse will make sure it is not mixed with any medicines or solutions with which it can interact.

Do not inject Crusia-AFT into a muscle.

Things to be careful of

Crusia-AFT is not interchangeable with other low molecular weight heparins (LMWH) products.

Ask your doctor whether there are any activities you should avoid while using Crusia-AFT, for example certain sports. Sometimes after an injury bleeding may occur inside your body without you knowing about it. Be sure to keep all of your doctor appointments. Your doctor will check your progress and may want to take some blood tests from time to time.

In case of overdose

If you use too much (overdose)

As Crusia-AFT is often given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, some patients may self-inject Crusia-AFT.

Tell your doctor or nurse or telephone the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have injected too much Crusia-AFT.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Crusia-AFT.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. **Ask your doctor or pharmacist to answer any questions you may have.**

Tell your doctor if you notice any of the following and they worry you:

- pain, bruising or irritation at the injection site after Crusia-AFT has been given
- hard inflamed nodules at the injection site
- itchy red rash at the injection site
- bleeding at the injection site
- itchy skin

If any of the following happen, stop using Crusia-AFT and tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- painful itchy red/purple rash at the injection site
- difficulty in breathing, symptoms of hayfever, feeling faint, itching hives, blisters or other symptoms of allergy
- bleeding (including nose bleeds or prolonged bleeding from cuts), bruising more easily than normal, red or dark brown urine, red or black bowel motions
- numbness (paralysis), problems with coordination, dizziness, tiredness, light-headedness, blurred vision, confusion or difficulty speaking

- severe abdominal, chest pain and headache
- nausea, diarrhoea, fever
- swelling of the hands, ankles or feet
- a fine widespread rash, especially noticeable on your mouth or eyes or sudden onset of white or blue colour in fingers or toes suggesting poor blood supply.

If you need to have had an anaesthetic injection in your back (spinal or epidural injection) while taking Crusia-AFT, this should be done in a hospital. Tell your doctor immediately if any of the following happen after an anaesthetic injection in your back:

- pain in the middle of your back (midline back pain)
- numbness and weakness in your legs (sensory and motor deficits)
- intestinal problems and problems in passing urine

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Crusia-AFT

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep Crusia-AFT in a cool dry place where the temperature stays below 25°C.

Keep the syringes in the pack until it is time to use them.

Do not freeze Crusia-AFT.

Do not leave Crusia-AFT in the car.

Keep Crusia-AFT away from direct sunlight.

Do not store Crusia-AFT or any other medicine in the bathroom, near a sink or stove or on a windowsill. Heat, light and dampness can destroy some medicines.

Keep Crusia-AFT 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

If your doctor tells you to stop using Crusia-AFT 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.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Crusia-AFT is available in the following range of presentations:

Crusia-AFT
20 mg/0.2 mL (anti-Xa: 2,000 IU) prefilled syringes, in packs of 10 and 50 syringes.
40 mg/0.4 mL (anti-Xa: 4,000 IU) prefilled syringes, in packs of 10, 30 and 50 syringes.
60 mg/0.6 mL (anti-Xa: 6,000 IU) prefilled syringes with graduated markings, in packs of 10 and 30 syringes.
80 mg/0.8 mL (anti-Xa: 8,000 IU) prefilled syringes with graduated markings, in packs of 10 and 30 syringes.
100 mg/1 mL (anti-Xa: 10,000 IU) prefilled syringes with graduated markings, in packs of 10 and 30 syringes.

Crusia-AFT (with automatic safety lock system)
20 mg/0.2 mL (anti-Xa: 2,000 IU) prefilled syringes, in packs of 10 and 50 syringes.
40 mg/0.4 mL (anti-Xa: 4,000 IU) prefilled syringes, in packs of 10, 30 and 50 syringes.
60 mg/0.6 mL (anti-Xa: 6,000 IU) prefilled syringes with graduated markings, in packs of 10 and 30 syringes.
80 mg/0.8 mL (anti-Xa: 8,000 IU) prefilled syringes with graduated markings, in packs of 10 and 30 syringes.
100 mg/1 mL (anti-Xa: 10,000 IU) prefilled syringes with graduated markings, in packs of 10 and 30 syringes.

Crusia-AFT Forte
120 mg/0.8 mL (anti-Xa: 12,000 IU) prefilled syringes with double graduated markings, in packs of 10 and 30 syringes.
150 mg/1 mL (anti-Xa: 15,000 IU) prefilled syringes with double graduated markings, in packs of 10 and 30 syringes.

Crusia-AFT Forte (with automatic safety lock system)
120 mg/0.8 mL (anti-Xa: 12,000 IU) prefilled syringes with double graduated markings, in packs of 10 and 30 syringes.
150 mg/1 mL (anti-Xa: 15,000 IU) prefilled syringes with double graduated markings, in packs of 10 and 30 syringes.

Ingredients

Active Ingredient:
Crusia-AFT contains enoxaparin sodium.

Inactive Ingredients:
Crusia-AFT also contains water for injections.

Sponsor details

Crusia-AFT is supplied in New Zealand by:

AFT Pharmaceuticals Ltd
Level 1, 129 Hurstmere Road
Takapuna
Auckland 0622
Phone: 0800 423 823

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