

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

CRUSIA 20, 2 000 IU (20 mg/0,2 ml) solution for injection in pre-filled syringes

CRUSIA 40, 4 000 IU (40 mg/0,4 ml) solution for injection in pre-filled syringes

CRUSIA 60, 6 000 IU (60 mg/0,6 ml) solution for injection in pre-filled syringes

CRUSIA 80, 8 000 IU (80 mg/0,8 ml) solution for injection in pre-filled syringes

CRUSIA 100, 10 000 IU (100 mg/1 ml) solution for injection in pre-filled syringes

Enoxaparin sodium

Sugar free

Read all of this leaflet carefully before you are given CRUSIA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- CRUSIA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CRUSIA is and what it is used or
2. What you need to know before you use CRUSIA
3. How to use CRUSIA
4. Possible side effects
5. How to store CRUSIA
6. Contents of the pack and other information

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1. What CRUSIA is and what it is used for

CRUSIA contains the active substance called enoxaparin sodium. This belongs to a group of medicines called 'low molecular weight heparin' or LMWH.

How CRUSIA work:

CRUSIA work in two ways:

1. Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2. Stopping new blood clots from forming in your blood.

CRUSIA can be used to:

- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
 - before and after an operation
 - when you have a short-term illness and will not be able to move around for some time.
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

2. What you need to know before you use CRUSIA

Do not use CRUSIA:

- if you are hypersensitive (allergic) to enoxaparin sodium, or any of the other ingredients of CRUSIA (listed in section 6)
- if you are hypersensitive (allergic) to heparin or other low molecular weight heparins such as

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nadroparin, tinzaparin or dalteparin

- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
 - stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke
- you are using CRUSIA to treat blood clots and are going to have within 24 hours:
 - a spinal or lumbar puncture
 - an operation with epidural or spinal anaesthesia.

Do not use CRUSIA if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using CRUSIA.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with CRUSIA:

CRUSIA syringes should not be interchanged with other 'low molecular weight heparins' such as nadroparin, tinzaparin or dalteparin, including other enoxaparin-containing medicines. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using CRUSIA if:

- you have any problem with your spine, or you have had spinal surgery
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure

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- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are currently using medicines which affect bleeding (see section 2, ‘Other medicines and CRUSIA’)
- you have endocarditis (an infection of the inner lining of the heart)
- you have had a heart valve fitted
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test).

Tests and checks

You may have a blood test before you start using CRUSIA and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

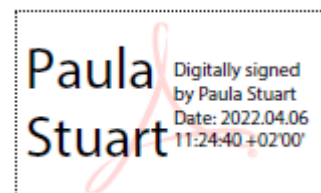
Children and adolescents

The safety and efficacy of CRUSIA has not been evaluated in children or adolescents.

Other medicines and CRUSIA

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking:



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- ibuprofen, diclofenac, ketorolac, or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, ‘Changing anticoagulant medicine’)
- dextran injection – used as a blood replacer
- prednisolone, dexamethasone, or other medicines used to treat asthma, rheumatoid arthritis, and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

Operations and anaesthetics

If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using CRUSIA.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before using CRUSIA.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

Driving and using machines

CRUSIA do not affect the ability to drive and operate machinery.

It is not always possible to predict to what extent CRUSIA may interfere with your daily activities.

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You should ensure that you do not engage in driving a vehicle or using machines until you are aware of the measure to which CRUSIA affects you.

3. How to use CRUSIA

Do not share medicines prescribed for you with any other person.

Always use CRUSIA exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor or nurse will normally give you CRUSIA. This is because it needs to be given as an injection.
- CRUSIA are usually given by injection underneath the skin (subcutaneous).
- CRUSIA can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- CRUSIA can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject CRUSIA into a muscle.

How much will be given to you

- Your doctor will decide how much CRUSIA to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of CRUSIA.

1) Treating blood clots that are in your blood

- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive CRUSIA.

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2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness

- The dose will depend on how likely you are to develop a clot. You will be given 2 000 IU (20 mg) or 4 000 IU (40 mg) of CRUSIA each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4 000 IU (40 mg) of CRUSIA each day.
- Your doctor will decide how long you should receive CRUSIA.

3) Stopping blood clots when you have unstable angina or after you have had a heart attack

- CRUSIA can be used for two different types of heart attack.
- The amount of CRUSIA given to you will depend on your age and the kind of heart attack you have had.

Non-Q-wave myocardial infarction type of heart attack:

- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive CRUSIA.

STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:

- An initial dose of 3 000 IU (30 mg) of CRUSIA will be given as an injection into your vein.
- At the same time, you will also be given CRUSIA as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive CRUSIA.

STEMI type of heart attack if you are 75 years old or older:

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- The usual dose is 75 IU (0,75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of CRUSIA given for the first two injections is 7 500 IU (75 mg).
- Your doctor will decide how long you should receive CRUSIA.

For patients that have an operation called percutaneous coronary intervention (PCI):

- Depending on when you were last given CRUSIA, your doctor may decide to give an additional dose of CRUSIA before a PCI operation. This is by injection into your vein.

4) Stopping blood clots from forming in the tubes of your dialysis machine

- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- CRUSIA are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session.

However, your doctor may give you a further dose of 50 IU to 100 IU (0,5 to 1 mg) for every kilogram of your bodyweight, if necessary.

Giving yourself an injection of CRUSIA

If you are able to give CRUSIA to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately.

Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

Before injecting yourself with CRUSIA

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container.
- Check the expiry date on the medicine. Do not use if the date has passed.

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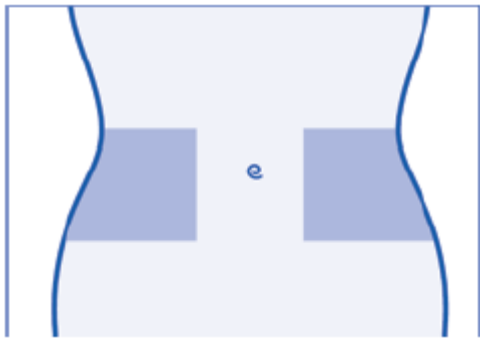
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- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe.
- Make sure you know how much you are going to inject.
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so, talk to your doctor or nurse.

Instructions on injecting yourself with CRUSIA:

1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.

- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.

3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

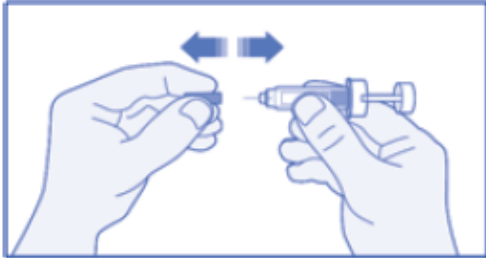
Selecting your dose

1) Carefully pull off the needle cap from the syringe. Throw away the cap.

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- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.

3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.

4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

Injecting

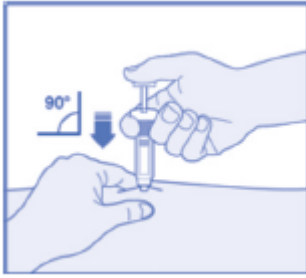
1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.

- Make sure you hold the skin fold throughout the injection.

2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.

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3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.

4) Remove the needle from the injection site by pulling it straight out. A protective sleeve will automatically cover the needle. You can now let go of the skin fold. The safety system only releases the protective sleeve when the syringe has been emptied by pressing the plunger all the way down.



When you have finished

- 1) To avoid bruising, do not rub the injection site after you have injected yourself.
- 2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

If you receive more CRUSIA than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the

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nearest hospital or poison centre.

If you missed a dose of CRUSIA

Do not give yourself a double dose on the same day to make up for a forgotten dose.

If you stop using CRUSIA

It is important for you to keep having CRUSIA injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

CRUSIA can have side effects.

Not all side effects reported for CRUSIA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being treated with CRUSIA, please consult your doctor, pharmacist, or other healthcare provider for advice.

If any of the following happens, stop taking / using CRUSIA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to CRUSIA. You may need urgent medical attention or hospitalisation.

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- tingling, numbness, and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- you have any bleeding that does not stop by itself
- if you have any sign of blockage of a blood vessel by a blood clot such as:
 - cramping pain, redness, warmth, or swelling in one of your legs – these are symptoms of deep vein thrombosis
 - breathlessness, chest pain, fainting or coughing up blood – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling.

Your doctor may request you perform a blood test to check your platelet count.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- headache
- increases in liver enzymes
- itchy red skin
- hives, urticaria
- bruising or pain at the injection site
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts

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- high platelet counts in the blood
- decreased red blood cell count
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- bleeding at wound sites
- nose bleeds
- blood in urine.

Less frequent side effects:

- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem
- hair loss
- large red irregularly shaped skin lesions with or without blisters
- purplish bruises under the skin
- inflammation and tissue damage (necrosis) of blood vessel walls (lumen) and associated skin
- osteoporosis (a condition where your bones are more likely to break) after long term use
- hard mass or lump at the injection site
- skin irritation (local irritation)
- increased potassium in your blood. Your doctor will be able to check this by carrying out a blood test.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

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If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CRUSIA.

5. How to store CRUSIA

- Store all medicines out of reach of children.
- Store at or below 25 °C. Do not freeze.
- Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see “What CRUSIA look like and contents of the pack”).
- Do not use this medicine after the expiry date which is stated on the carton and the vial after “EXP”. The expiry date refers to the last day of that month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Content of the pack and other information

What CRUSIA contains

The active substance is enoxaparin sodium.

Each ml contains 100 mg enoxaparin sodium, equivalent to 10 000 IU of anti-Xa activity.

CRUSIA 20: Each pre-filled syringe of 0,2 ml contains 2 000 IU (20 mg) of enoxaparin sodium.

CRUSIA 40: Each pre-filled syringe of 0,4 ml contains 4 000 IU (40 mg) of enoxaparin sodium.

CRUSIA 60: Each pre-filled syringe of 0,6 ml contains 6 000 IU (60 mg) of enoxaparin sodium.

CRUSIA 80: Each pre-filled syringe of 0,8 ml contains 8 000 IU (80 mg) of enoxaparin sodium.

CRUSIA 100: Each pre-filled syringe of 1 ml contains 10 000 IU (100 mg) of enoxaparin sodium.

The other ingredient is water for injections.

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What CRUSIA looks like and contents of the pack

CRUSIA is a clear, sterile solution, free from visible particulate matter.

CRUSIA is packed in clear, transparent Type I glass pre-filled syringes with black chlorobutyl rubber stopper fitted with injection needle with or without an automatic safety device for some presentations.

The needle shield is made of synthetic rubber and a rigid cover of polypropylene.

Prefilled syringes are stored in plastic trays and carton boxes.

CRUSIA 20: 0,2 mL solution for injection in a 0,5 mL pre-filled syringe without scale. Pack sizes of 2, 10 and 50 syringes.

CRUSIA 40: 0,4 mL solution for injection in a 0,5 mL pre-filled syringe without scale. Pack sizes of 2, 10, 30 and 50 syringes.

CRUSIA 60: 0,6 mL solution for injection in a 1,0 mL graduated pre-filled syringe. Pack sizes of 2, 10 and 30 syringes.

CRUSIA 80: 0,8 mL solution for injection in a 1,0 mL graduated pre-filled syringe. Pack sizes of 2, 10 and 30 syringes.

CRUSIA 100: 1,0 mL solution for injection in a 1,0 mL graduated pre-filled syringe. Pack sizes of 2, 10 and 30 syringes.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

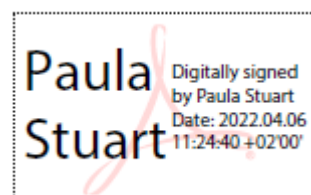
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CRUSIA 20 - 550009

CRUSIA 40 - 550010

CRUSIA 60 - 550011

CRUSIA 80 - 550012

CRUSIA 100 - 550013

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