

## What is in this leaflet

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## What CRUSIA is used for.

CRUSIA contains enoxaparin sodium as the active ingredient which belongs to a group of a medicine called Low Molecular Weight Heparins (LMWH).

Your doctor may have prescribed CRUSIA to **prevent** the following conditions of:

- Formation of blood clots in the veins (thromboembolic disorders), including in orthopedic and general surgery.
- Formation of blood clots in the veins of bedridden patients admitted because of a sudden illness, including heart failure, acute respiratory failure, severe infections or rheumatic diseases.
- Blood clotting (coagulation) in the extracorporeal circulation by hemodialysis (kidney replacement therapy).

Your doctor may have prescribed CRUSIA to **treat** the following conditions of:

- Blood clots in the veins (deep vein thrombosis) with or without pulmonary embolism (a blockage of an artery by a blood clot).
- A sudden painful feeling tightness in the chest (unstable angina) and some form of a heart attack (myocardial infarction without Q-wave), in combination with acetylsalicylic acid (aspirin).
- An acute heart attack (STEMI: ST-segment Elevation Myocardial Infarction) in patient not for subsequent coronary angioplasty-

Percutaneous Coronary Intervention (PCI).

## How CRUSIA works?

### CRUSIA works in two ways;

- i. Stopping existing blood clots from getting any bigger. This helps your body to break them down and stop them causing you harm.
- ii. Stopping blood clots forming in your blood.

### Before you use CRUSIA

- When you must not use it?

Do not use CRUSIA if:

- If you are allergic (hypersensitive) to
  - i. the active ingredient enoxaparin sodium or any of the other ingredients of CRUSIA.
  - ii. heparin or other Low Molecular Weight Heparins.
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue:
  - You have a problem with bruising or bleeding too easily.
  - You have an ulcer in your stomach or gut (intestine).
  - You have had a stroke caused by bleeding in the brain.
  - You have kidney problems (see "People with kidney problems").
  - You have an infection in your heart.
  - You are using heparin to treat blood clots (see "Taking other medicines")

### Pregnancy and lactation

Talk to your doctor before you are given this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

You should not use this medicine if you are pregnant and have a mechanical heart valve as you may be at increased risk of developing blood clots. Your doctor should discuss this with you.

You should not breast-feed whilst using CRUSIA. If you are planning to breastfeed, talk to your doctor, pharmacist or nurse.

**Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.**

### - Before you start use it

Check with your doctor or pharmacist before taking CRUSIA if you are experiencing or have experienced in the past of any of the following conditions:

- If you have severe abnormalities in blood clotting.
- If this medicine with an anesthetic (anesthesia) was used, consult your doctor immediately if you experience the following symptoms occur: pain in the middle of the back, motor disorders (movements) and sensory disturbances (numbness or weakness of the lower limbs), functional disorders of the bladder or of the intestine.
- If you are elderly, given the increased risk of bleeding.
- If you suffer from reduced kidney function or liver (renal or hepatic).
- If you are underweight or overweight (<40kg and > 100kg).
- If you have severe, uncontrolled high blood pressure.
- If you have a stomach or intestinal ulcer or have had.
- If you have recently had a heart attack.
- If you have certain disorders of the retina caused by diabetes or bleeding (hemorrhagic or diabetic retinopathy).
- If you have mechanical heart valves, especially if you are pregnant. Always consult your doctor.
- If you need to undergo surgical interventions at the level of the nerves, eyes, or the coronary artery.
- In some cases where there is a shortage of platelets. Your doctor will regularly check your blood platelets.
- If you have a history of spinal (with respect to the spine) surgery or has spinal deformity.
- If you are taking other medication, carefully read the section "Taking other medicines".

Enoxaparin Sodium Solution for Injection in Pre-filled Syringe (20mg/0.2ml, 40mg/0.4ml, 60mg/0.6ml, 80mg/0.8ml)

• **Taking other medicines**

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. This is because CRUSIA can affect the way some other medicines work. Also, some medicines can affect the way CRUSIA works. For CRUSIA, be aware of the following:

**Stop using these medicines unless your doctor tells you otherwise:**

- Heparin - used to treat blood clots.

**Tell your doctor if you are taking any of the following medicines:**

- Warfarin – used for thinning the blood
- Aspirin, dipyridamole, clopidogrel or other medicines - used to stop blood clots forming.
- Dextran injection - used to replace blood volume.
- Ibuprofen, diclofenac, ketorolac or other medicines - used to treat pain and swelling in arthritis and other conditions.
- Water tablets (diuretics) such as spironolactone, triamterene or amiloride. These may increase the levels of potassium in your blood when taken with CRUSIA.

Your doctor may change one of your medicines or take regular blood tests to check that taking these medicines with CRUSIA is not causing you any harm.

**Operations and anesthetics**

If you are going to have a spinal puncture or an operation where an epidural or spinal anesthetic is used, tell your doctor that you are having CRUSIA. Tell also your doctor if you have any problem with your spine or if you have ever had spinal surgery

• **How to use CRUSIA**

Use CRUSIA exactly as your doctor has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

**Method and route of administration:**

CRUSIA is given subcutaneously (under the skin), intravenously (into a vein) or

administered through the arterial line of the dialysis unit. The route of administration depends on the indication for which you are being treated as mentioned under "How much to use."

CRUSIA should not be given intramuscularly (into the muscle). The pre-filled syringes are ready to use and must not be vented before use.

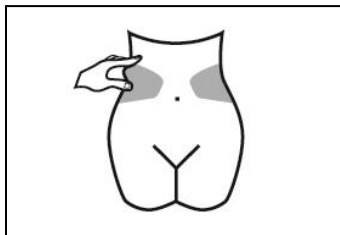
**INSTRUCTION FOR USE**

**How to give 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.

**Preparing the injection site**

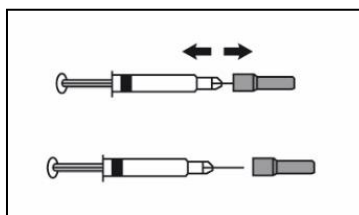
The recommended injection site is in the fat of the abdomen. This must be at least 5 cm from the navel to the outside and to one side or the other.



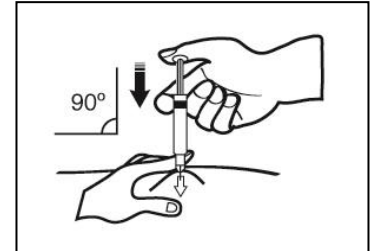
For injection, wash your hands. Clean (without rubbing) the chosen injection site with an alcohol swab. Choose a different site for each injection of the abdomen.

**Technique for subcutaneous injection (prefilled syringes):**

Carefully remove needle cap by firmly pulling it straight out and discard. **(DO NOT EXPEL THE AIR BUBBLE)**

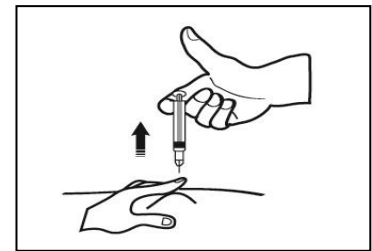


Sit or lie in a comfortable position. Take a fold of skin (fat from the abdomen) between your thumb and forefinger. Insert the full length of the needle vertically into the skin fold (90° angle).



Press down on the plunger with your thumb until the syringe is empty and the abdominal wall remains folded until the injection is done. **(DO NOT RUB THE INJECTION SITE)**

Remove the syringe from the injection site. Throw the syringe away immediately in the nearest sharp collector.



• **How much to use**

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

**Adults:**

**To reduce the risk of blood clots in the veins (thromboembolic disorders):** One subcutaneous (subcutaneous) injection of 2000IU (20mg) or 4000IU (40mg) daily.

- In order to prevent blood clots in the veins that may occur after some operations, it is possible that an initial injection is given 12 hours before the operation.
- In the orthopedic surgery has been found advantageous to initial therapy

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with 4000IU (40mg) once daily to continue for 4-5 weeks.

- For blood clots in the veins occur in bedridden patients, the recommended dose of CRUSIA is one subcutaneous injection of 4000IU (40mg) per day. Treatment is prescribed for a minimum of 6 days, and continued until you can step back (with a maximum of 14 days).
- Treatment with CRUSIA is usually prescribed for an average period of 7 to 10 days. A longer duration of treatment may be indicated in some patients.
- To treat blood clots.

**Treatment of blood clots in the veins (deep vein thrombosis) with or without pulmonary embolism:**

The dosage:

- A subcutaneous injection of 100 IU CRUSIA per kg of body weight every 12 hours (2 times per day) for 10 days.

**In angina (unstable angina) or non-Q-wave heart attack:**

The recommended dose is 100 IU per kg of body weight administered subcutaneously every 12 hours, in combination with acetylsalicylic acid (75 to 325 mg per day) by the oral route.

**In acute myocardial infarction with ST-segment elevation (STEMI):**

The recommended dose is a single intravenous injection of 3000 IU (30mg), together with a subcutaneous injection of 100 IU/kg of body weight. This is followed by a subcutaneous administration of 100 IU/kg of body weight every 12 hours.

(With a maximum dose of CRUSIA 10000 IU (100mg) for each of the first two subcutaneous administrations, followed by subcutaneous administration of 100 IU/ kg of body weight for the following doses). For the dose in patients aged 75 years, see section "Elderly"

The recommended treatment duration is 8 days or until you leave the hospital, if the hospitalization period is less than 8 days.

**For patients subsequently treated with coronary angioplasty:**

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

**To prevent blood clots forming in the tubes of your dialysis machine in hemodialysis:**

An initial dose of 100 IU/ kg of body weight will be added to the tube leaving the body (arterial line) at the beginning of the session. This dose is normally sufficient for a hemodialysis session for 4 hours. However, your doctor may give you a further dose of maximum of 100 IU/kg if necessary.

If you have a high risk of bleeding (e.g. in pre-and postoperative dialysis or evolutionary hemorrhagic syndrome), the dialysis treatments may be performed at a lower dose (50 IU/ kg for double vascular access or 75 IU/ kg in single vascular access).

**Children:**

The safety and effectiveness of CRUSIA in children have not yet been demonstrated.

**Elderly:**

**Treatment of acute myocardial infarction with ST-segment elevation:** Do not use single intravenous injection in patients aged 75 years. Use a subcutaneous administration of 75 IU/ kg of body weight every 12 hours (with a maximum dose of 7500 IU (75mg) CRUSIA for each of the first two subcutaneous administrations, followed by subcutaneous administration of 75 IU/ kg of body weight for the following doses)

**Hepatic impairment:**

CRUSIA should be used cautiously in patients with hepatic impairment.

**Renal impairment:**

If you have a reduced effect exhibits of your kidneys, your doctor may reduce the dose of CRUSIA to minimize the risk of bleeding.

- When to use it  
Use as directed by your doctor or pharmacist. Administration of the medicine at approximately at the same time every day are recommended.
- How long to use it  
Continue taking CRUSIA for as long as your doctor recommends.
- If you forget to use it  
Consult your doctor or pharmacist on what you should do if you forget to use it.  
**Do not take a double dose to make up for the missed dose.** This may increase the chance of getting an unwanted side effect.
- If you use too much (overdose)  
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

**While you are using it**

- Things you must do  
Tell all the doctors, dentists and pharmacists treating you that you are taking CRUSIA.

Using CRUSIA may affect the results of some of the blood tests. If you are going to have a blood test, it is important to tell your doctor you are using CRUSIA.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do  
Do not stop taking the medicine unless advised by your doctor. If you do so, you could get a blood clot which can be very dangerous.

Do not take any new medicines without consulting your doctor.

Do not give CRUSIA to anyone else, even if they have the same symptoms or condition as you.

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• Things to be careful of

*Driving and using machines*

CRUSIA has no influence on the ability to drive and use machines.

**Side effects**

Like all medicines, CRUSIA can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Common side effects:

- Bleeding a lot from a wound.
- A painful rash of dark red spots under the skin which do not go away when you put pressure on them. You may also notice pink patches on your skin. These are more likely to appear in the area you have been injected with CRUSIA.
- Allergic reactions which include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you have had a spinal puncture or a spinal anaesthetic and notice tingling, numbness and muscular weakness, particularly in the lower part of your body.
- You bruise more easily than usual. This could be because of a blood problem (thrombocytopenia).
- You have pain, swelling or irritation in the area you have been injected with CRUSIA. This normally gets better after a few days.
- Changes in the results of blood tests done to check how your liver is working. These usually go back to normal after you stop having CRUSIA.
- Changes in the potassium levels in your blood.
- If CRUSIA is used for a long period of time, it may increase the risk of you getting a condition called 'osteoporosis'. This is when your bones are more likely to break.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

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

**Ask your doctor or pharmacist to answer any questions you may have.**

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [np.ra.moh.gov.my](http://np.ra.moh.gov.my) (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

**Storage and Disposal of CRUSIA**

- Storage

Keep out of the reach and sight of children.

Store in a dry place at a temperature not exceeding 25 °C and do not freeze the pre-filled syringes.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like

**CRUSIA 2000 IU/ 4000 IU/ 6000 IU & 8000 IU:** Boxes of clear, colorless to pale yellow solution in 10 pre-filled syringes for subcutaneous or intravenous injection.

- Ingredients

- Active ingredient:  
Enoxaparin Sodium

- Each pre-filled syringe contains enoxaparin sodium 2000 IU (equivalent to 20 mg) in 0.2 mL water for injections.
- Each pre-filled syringe contains enoxaparin sodium 4000 IU equivalent to 40 mg) in 0.4 mL water for injections.
- Each pre-filled syringe contains enoxaparin sodium 6000 IU (equivalent to 60 mg) in 0.6 mL water for injections.
- Each pre-filled syringe contains enoxaparin sodium 8000 IU (equivalent to 80 mg) in 0.8 mL water for injections.

- Inactive ingredients

Water for Injections Ph.Eur

- MAL Number:

- **MALxxxxxxxAZ-** CRUSIA 2000 IU (20mg)/0.2ml Solution for Injection in Pre-filled Syringe
- **MALxxxxxxxAZ-** CRUSIA 4000 IU (40mg)/0.4ml Solution for Injection in Pre-filled Syringe
- **MALxxxxxxxAZ-** CRUSIA 6000 IU (60mg)/0.6ml Solution for Injection in Pre-filled Syringe
- **MALxxxxxxxAZ-** CRUSIA 8000 IU (80mg)/0.8ml Solution for Injection in Pre-filled Syringe

**Manufactured by:**

**ROVI CONTRACT MANUFACTURING, S.L.**

Julian Camarillo, 35,  
28037 Madrid  
España / Spain

**Manufactured for:**

**LABORATORIOS FARMACEUTICOS ROVI, S.A.**

Julian Camarillo, 35  
28037 Madrid  
España / Spain

**Product Registration Holder:**

**UNIMED SDN BHD**

No.53 Jalan Tembaga SD 5/2B,  
Bandar Sri Damansara, 52200 Kuala Lumpur

**Date of Revision**

01/09/2020

**RiMUP Serial Number:**

NPRA (R3) 20/015