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 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 works:

CRUSIA works 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 nadroparin, tinzaparin or dalteparin

- if 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
- if you have antibodies against enoxaparin in your blood
- if 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
- if 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
- 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:

- 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

- 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 does 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. 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** is 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**.

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:

- 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** is 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.

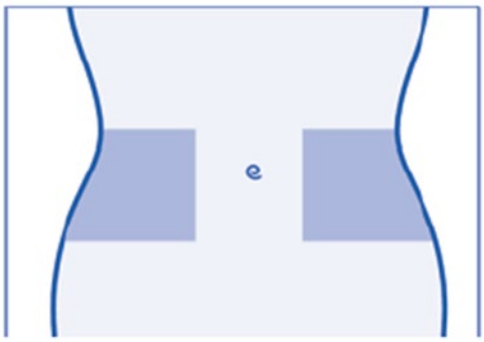
Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

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.
- 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 5 cm 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.



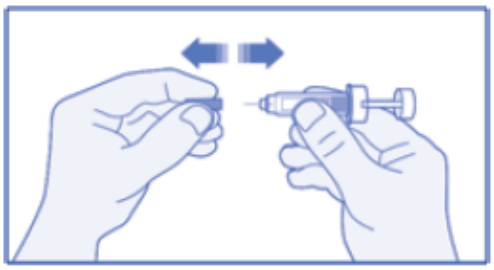
2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.

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.

- 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.

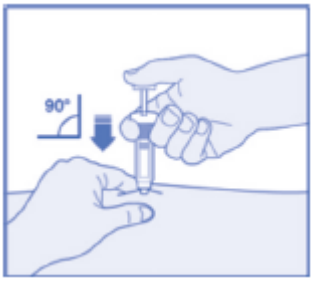
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

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.



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 overdosage, consult your doctor or pharmacist. If neither is available, contact the 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.

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
- 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

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 looks 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.

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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Registration/Application number

CRUSIA 20: 55/8.2/0009

CRUSIA 40: 55/8.2/0010

CRUSIA 60: 55/8.2/0011

CRUSIA 80: 55/8.2/0012

CRUSIA 100: 55/8.2/0013

PIL 13 March 2023

PASIËNT INLIGTINGSBLAD

SKEDULERINGSTATUS S4

CRUSIA 20, 2 000 IE (20 mg/0,2 mL) oplossing vir inspuiting in voorafgevulde spuite

CRUSIA 40, 4 000 IE (40 mg/0,4 mL) oplossing vir inspuiting in voorafgevulde spuite

CRUSIA 60, 6 000 IE (60 mg/0,6 mL) oplossing vir inspuiting in voorafgevulde spuite

CRUSIA 80, 8 000 IE (80 mg/0,8 mL) oplossing vir inspuiting in voorafgevulde spuite

CRUSIA 100, 10 000 IE (100 mg/1 mL) oplossing vir inspuiting in voorafgevulde spuite

Enoksapariennatrium

Suikervry

Lees die hele voubiljet noukeurig deur voordat CRUSIA aan u gegee word

- Bewaar hierdie voubiljet. U sal dit dalk weer moet lees.
- As u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleër of ander gesondheidsorg kundige.
- **CRUSIA** is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie voubiljet

6. Inhoud van die verpakking en ander inligting

1. Wat CRUSIA is en waarvoor dit gebruik word

CRUSIA bevat die aktiewe bestanddeel enoksapariennatrium. Dit behoort aan 'n groep medisyne wat 'lae molekulêre gewig heparien' of LMGH genoem word.

Hoe CRUSIA werk:

CRUSIA werk op twee maniere:

1. Voorkom dat bestaande bloedklonte groter word. Dit help u liggaam om hulle af te breek en keer dat dit skade by u veroorsaak.
2. Om te keer dat nuwe bloedklonte in u bloed vorm.

CRUSIA kan gebruik word om:

- Bloedklonte te behandel wat in u bloed is
- Die vorming van bloedklonte in u bloed te stop in die volgende situasies:
    - voor en na 'n operasie
    - wanneer u aan 'n korttermyn siekte ly en vir 'n geruime tyd nie kan rondbeweeg nie
- Bloedklonte te voorkom wanneer u onstabiele angina het (waar daar nie genoeg bloed by u hart kom nie) of na 'n hartaanval
- Bloedklonte te voorkom in die buise van u dialise masjien (gebruik vir mense met ernstige nierprobleme).

2. Wat u moet weet voordat u CRUSIA gebruik

Moenie CRUSIA gebruik:

- indien u hipersensitief (allergies) is vir enoksapariennatrium, of enige van die ander bestanddele van **CRUSIA** nie (gelys in afdeling 6)
- indien u hipersensitief (allergies) is vir heparien of ander lae molekulêre gewig hepariene soos nadroparien, tinzaparien of dalteparien nie

- indien u 'n reaksie op heparien gehad het wat 'n ernstige afname in die aantal stollingselle (plaatjies) binne die afgelope 100 dae veroorsaak het nie
- indien u teenliggaampies teen enoksaparien in u bloed het nie
- indien u swaar bloei of 'n toestand het met 'n hoë risiko van bloeding nie, soos:
    - maagseer, onlangse operasie van die brein of oë, of onlangse bloeding beroerte
- indien u **CRUSIA** gebruik om bloedklonte te behandel en binne 24 uur gaan die volgende ondergaan nie:
    - 'n spinale of lumbale punksie
    - 'n operasie met epidurale of spinale narkose.

Moenie **CRUSIA** gebruik indien enige van die bogenoemde op u van toepassing is nie. Indien u nie seker is nie, raadpleeg u dokter of apteker voordat u **CRUSIA** gebruik.

Waarskuwings en voorsorgmaatreëls

Lig u dokter of gesondheidsorg kundige in voordat u die inspuiting gegee word:

Spesiale sorg moet geneem word met **CRUSIA**:

CRUSIA-spuite moet nie met ander 'lae molekulêre gewig hepariene' soos nadroparien, tinzaparien of dalteparien, insluitend ander enoksaparien-bevattende medisyne, uitgeruil word nie. Dit is omdat hulle nie presies dieselfde is nie en nie dieselfde aktiwiteit en instruksies vir gebruik het nie.

Raadpleeg u dokter of apteker voordat CRUSIA gebruik word indien:

- u enige probleem met u ruggraat het, of u het ruggraatchirurgie gehad
- u al ooit 'n reaksie op heparien gehad het wat 'n ernstige afname in die aantal stollingselle (plaatjies) veroorsaak het.
- u 'n geskiedenis van maagseer het
- u onlangs 'n beroerte gehad het
- u hoë bloeddruk het
- u diabetes of probleme met bloedvate in die oog het wat veroorsaak word deur diabetes (genoem diabetiese retinopatie)

- u onlangs 'n operasie aan u oë of brein gehad het
- u tans medisyne gebruik wat bloeding beïnvloed (sien afdeling 2, **Ander medisyne en CRUSIA**)
- u endokarditis het ('n infeksie van die binneste membraan van die hart)
- u 'n hartklep laat vervang het
- u bejaard is (bo 65 jaar oud) en veral indien u ouer as 75 jaar is
- u nierprobleme het
- u lewerprobleme het
- u ondergewig of oorgewig is
- u hoë vlakke van kalium in u bloed het (dit kan met 'n bloedtoets nagegaan word).

Toetse en ondersoeke

U kan 'n bloedtoets ondergaan voordat u **CRUSIA** begin gebruik en met tussenposes terwyl u dit gebruik; dit is om die vlak van die stollingselle (plaatjies) en kalium in u bloed na te gaan.

Kinders en adolessente

Die veiligheid en doeltreffendheid van **CRUSIA** is nie by kinders of adolessente geëvalueer nie.

Ander medisyne en CRUSIA

Lig altyd u gesondheidsorg kundige in indien u enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Lig u dokter in indien u die volgende gebruik:

- ibuprofen, diklofenak, ketorolak, of ander medisyne bekend as nie-steroïed anti-inflammatoriese medisyne wat gebruik word om pyn en swelling in artritis en ander toestande te behandel
- warfarin – gebruik om die bloed te verdun
- aspirien (ook bekend as asetielsalisielsuur of ASA), klopidogrel of ander medisyne wat gebruik word om te keer dat bloedklonte vorm

- dekstraan-inspuiting – gebruik as 'n bloedvervanger
- prednisoloon, deksametasoon of ander medisyne wat gebruik word om asma, rumaties artritis en ander toestande te behandel
- medisyne wat kaliumvlakke in u bloed verhoog, soos kaliumsoute, waterpille en sommige medisyne vir hartprobleme.

Operasies en narkose

Indien u 'n ruggraat- of lumbale punksie gaan kry, of 'n operasie waar 'n epidurale of spinale verdower gebruik word, lig u dokter in dat u **CRUSIA** gebruik.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, dink u is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat u **CRUSIA** gebruik.

Indien u swanger is en 'n meganiese hartklep het, kan u 'n hoër risiko hê om bloedklonte te ontwikkel. U dokter moet dit met u bespreek.

Bestuur van ‘n voertuig en gebruik van masjinerie

CRUSIA beïnvloed nie die vermoë om ‘n voertuig te bestuur en masjinerie te hanteer nie.

Dit is nie altyd moontlik om te voorspel tot watter mate **CRUSIA** met u daaglikse aktiwiteite kan inmeng nie. U moet verseker dat u nie 'n voertuig bestuur of masjiene gebruik totdat u bewus is van die mate waarin **CRUSIA** u affekteer nie.

3. Hoe om CRUSIA te gebruik

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Gebruik altyd **CRUSIA** presies soos u dokter vir u gesê het. Maak seker by u dokter of apteker indien u nie seker is nie.

- U dokter of verpleegster sal gewoonlik **CRUSIA** vir u toedien. Dit is omdat dit as 'n inspuiting gegee moet word.
- **CRUSIA** word gewoonlik deur inspuiting onder die vel (subkutaan) toegedien.
- **CRUSIA** kan toegedien word deur dit in u aar te spuit (binneaars) na sekere tipes hartaanval of operasies.
- **CRUSIA** kan aan die begin van 'n dialisesessie by die buis gevoeg word wat die liggaam verlaat (arteriële lyn).
- Moenie **CRUSIA** in 'n spier spuit nie.

Hoeveel sal vir u gegee word

- U dokter sal besluit hoeveel **CRUSIA** om vir u te gee. Die volume sal afhang van die rede waarom dit gebruik word.
- Indien u probleme met u niere het, kan u 'n kleiner volume **CRUSIA** gegee word.

1) Behandeling van bloedklonte wat in u bloed is

- Die gewone dosis is 100 IE (1 mg) vir elke kilogram van u liggaamsgewig twee keer per dag.
- U dokter sal besluit vir hoe lank u **CRUSIA** moet ontvang.

2) Stop die vorming van bloedklonte in u bloed tydens operasies of periodes van beperkte mobiliteit as gevolg van 'n siekte

- Die dosis sal afhang van hoe waarskynlik dit is dat u 'n bloedklont sal ontwikkel. U sal elke dag 2 000 IE (20 mg) of 4 000 IE (40 mg) **CRUSIA** gegee word.
- Indien u 'n operasie gaan ondergaan, sal u eerste inspuiting gewoonlik 2 uur of 12 uur voor u operasie gegee word.
- Indien u beperkte mobiliteit het weens siekte, sal u normaalweg 4 000 IE (40 mg) **CRUSIA** elke dag gegee word.

- U dokter sal besluit vir hoe lank u **CRUSIA** moet ontvang.

3) Stop bloedklonte wanneer u onstabiele angina het of nadat u 'n hartaanval gehad het

- **CRUSIA** kan vir twee verskillende tipes hartaanval gebruik word.
- Die volume **CRUSIA** wat aan u gegee word, sal afhang van u ouderdom en die soort hartaanval wat u gehad het.

Nie-Q-golf miokardiale infarksie tipe hartaanval:

- Die gewone dosis is 100 IE (1 mg) vir elke kilogram van u liggaamsgewig elke 12 uur.
- U dokter sal u gewoonlik vra om ook aspirien (asetielsalisielsuur) te neem.
- U dokter sal besluit vir hoe lank u **CRUSIA** moet ontvang.

STEMI (ST segment Verhoogde Miokardiale Infarksie) tipe hartaanval as u jonger as 75 jaar oud is:

- 'n Aanvangsdosis van 3 000 IE (30 mg) **CRUSIA** sal as 'n inspuiting in u aar gegee word.
- Terselfdertyd sal u ook **CRUSIA** as 'n inspuiting onder u vel (subkutane inspuiting) gegee word. Die gewone dosis is 100 IE (1 mg) vir elke kilogram van u liggaamsgewig, elke 12 uur.
- U dokter sal u gewoonlik vra om ook aspirien (asetielsalisielsuur) te neem.
- U dokter sal besluit hoe lank u **CRUSIA** moet ontvang.

STEMI tipe hartaanval as u 75 jaar oud of ouer is:

- Die gewone dosis is 75 IE (0,75 mg) vir elke kilogram van u liggaamsgewig, elke 12 uur.
- Die maksimum volume **CRUSIA** gegee vir die eerste twee inspuitings is 7 500 IE (75 mg).
- U dokter sal besluit vir hoe lank u **CRUSIA** moet ontvang.

Vir pasiënte wat 'n operasie genaamd perkutane koronêre intervensie (PKI) ondergaan:

- Afhangende van wanneer laas **CRUSIA** aan u gegee is, kan u dokter besluit om 'n bykomende dosis **CRUSIA** voor 'n PKI-operasie te gee. Dit sal wees om dit in die aar te spuit.

4) Om te keer dat bloedklonte in die buise van u dialise masjien vorm

- Die gewone dosis is 100 IE (1 mg) vir elke kilogram van u liggaamsgewig.
- **CRUSIA** word by die buis gevoeg wat die liggaam verlaat (arteriële lyn) aan die begin van 'n dialise-sessie. Hierdie volume is gewoonlik genoeg vir 'n sessie van 4 uur. U dokter kan u

egter 'n verdere dosis van 50 IE tot 100 IE gee (0,5 tot 1 mg) vir elke kilogram van u liggaamsgewig, indien nodig.

Om uself 'n inspuiting van CRUSIA te gee

Indien u **CRUSIA** aan uself kan toedien, sal u dokter of verpleër u wys hoe om dit te doen. Moenie probeer om uself in te spuit as u nie opgelei is om dit te doen nie. Indien u nie seker is wat om te doen nie, raadpleeg dadelik u dokter of verpleër.

Deur die inspuiting korrek onder die vel toe te dien (genoem "subkutane inspuiting") sal help om pyn en kneusing by die inspuitplek te verminder.

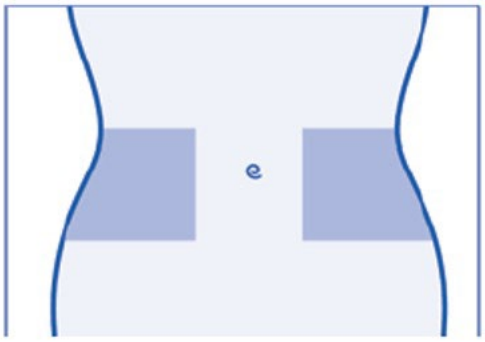
Voordat u uself met CRUSIA inspuit

- Versamel die items wat u nodig het: inspuiting, alkohol depper of seep en water, en ‘n houer vir skerp voorwerpe (“sharps” houer).
- Gaan die vervaldatum op die medisyne na. Moenie gebruik indien die datum verstryk het nie.
- Kyk of die inspuiting nie beskadig is nie en dat die medisyne daarin 'n helder oplossing is. Indien nie, gebruik 'n ander inspuiting.
- Maak seker u weet hoeveel u gaan inspuit.
- Gaan u maag na om te sien of die laaste inspuiting enige rooiheid, verandering in velkleur, swelling of uitskeidings veroorsaak het of steeds pynlik is. Indien wel, raadpleeg u dokter of verpleër.

Instruksies om uself met CRUSIA in te spuit:

1) Kies 'n area aan die regter- of linkerkant van u maag. Dit moet ten minste 5 sentimeter weg wees van u naeltjie, en na u sye se kant toe.

- Moenie uself binne 5 cm van u naeltjie of rondom bestaande letsels of kneusplekke inspuit nie.
- Verander die plek waar u inspuit tussen die linker- en regterkant van u maag, afhangende van die area wat u laas ingespuit het.



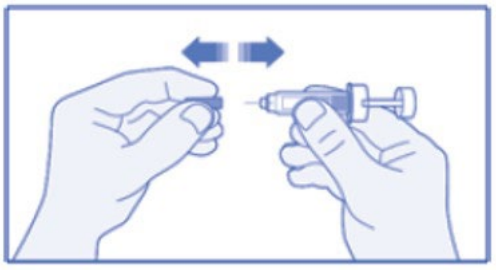
2) Was u hande. Maak die area wat u gaan spuit skoon (moenie vryf nie) met 'n alkohol-depper of seep en water.

3) Sit of lê in 'n gemaklike posisie sodat u ontspanne is. Maak seker u kan die plek sien wat u gaan inspuit. 'n Gemaklike stoel, leunstoel of bed met kussings gestut, is ideaal.

Kies u dosis

1) Trek die naald-doppie versigtig van die inspuiting af. Gooi die doppie weg.

- Voordat u uself inspuit, moenie op die druksuier druk om van lugborrels ontslae te raak nie. Dit kan lei tot 'n verlies van medisyne.
- Sodra u die doppie verwyder het, moenie toelaat dat die naald aan enigiets raak nie. Dit is om seker te maak die naald bly skoon (steriel).



2) Wanneer die volume medikasie in die inspuiting reeds ooreenstem met u voorgeskrewe dosis, is dit nie nodig om die dosis aan te pas nie. U is nou gereed om te spuit.

3) Wanneer die dosis van u liggaamsgewig afhang, moet u dalk die dosis in die spuit aanpas om by die voorgeskrewe dosis te pas. In daardie geval kan u van enige ekstra medisyne ontslae raak deur die spuit na onder te hou (om die lugborrel in die spuit te behou) en spuit die ekstra hoeveelheid in 'n houer uit.

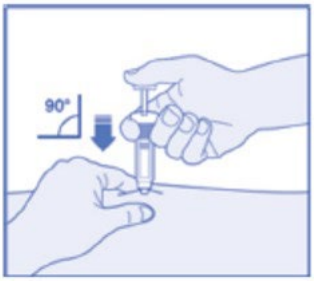
4) 'n Druppel mag by die punt van die naald verskyn. Indien dit gebeur, verwyder die druppel voor u spuit deur op die inspuiting te tik met die naald na onder. U is nou gereed om te spuit.

Spuit in

1) Hou die inspuiting in die hand waarmee u skryf (soos 'n potlood). Met u ander hand, knyp die skoongemaakte area van u maag saggies tussen u wysvinger en duim vas om ’n vou in die vel te maak.

- Maak seker u hou die velvou heeltyd vas gedurende die inspuiting.

2) Hou die inspuiting vas sodat die naald reguit na onder wys (vertikaal teen 'n 90 °-hoek). Steek die volle lengte van die naald in die velvou in.



3) Druk die druksuier met u duim af. Dit sal die medikasie in die vetweefsel van die maag stuur. Voltooi die inspuiting deur al die medisyne in die spuit in te spuit.

4) Verwyder die naald van die inspuitplek deur dit reguit uit te trek. 'n Beskermende bedekking sal outomaties die naald toemaak. U kan nou die velvou los. Die veiligheidsstelsel stel die beskermende bedekking slegs vry wanneer die inspuiting leeggemaak is deur die druksuier heeltemal af te druk.

Wanneer u klaar is

1) Om kneusing te vermy, moenie die inspuitplek vryf nadat u uself ingespuit het nie.

2) Gooi die gebruikte inspuiting in 'n houer vir skerp items (“sharps” houer). Maak die houer se deksel styf toe en plaas die houer buite bereik van kinders. Wanneer die houer vol is, gooi dit weg soos u dokter of apteker u ingelig het.

Enige ongebruikte medisyne of afvalmateriaal moet in ooreenstemming met plaaslike vereistes weggegooi word.

Indien u meer CRUSIA ontvang as wat u behoort

In die geval van oordosis, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.

Indien u 'n dosis CRUSIA gemis het

Moenie uself 'n dubbele dosis op dieselfde dag gee om op te maak vir 'n vergete dosis nie.

Indien u ophou om CRUSIA te gebruik

Dit is belangrik vir u om aan te hou om **CRUSIA**-inspuitings te kry totdat u dokter besluit om dit te stop. Indien u dit staak, kan u 'n bloedklont kry wat baie gevaarlik kan wees.

Indien u enige verdere vrae het oor die gebruik van hierdie medisyne, vra u dokter of apteker of verpleër.

4. Moontlike newe-effekte

CRUSIA kan newe-effekte hê.

Nie alle newe-effekte wat vir **CRUSIA** aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid versleg of indien u enige nadelige effekte ervaar terwyl u met **CRUSIA** behandel word, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, hou op om **CRUSIA** te gebruik en lig u dokter dadelik in of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal
- uitslag of jeuk.

Dit is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op **CRUSIA** gehad. U mag dalk dringende mediese aandag of hospitalisasie benodig.

Lig u dokter dadelik in of gaan na die ongevalle-afdeling by u naaste hospitaal as u enige van die volgende opmerk:

- tinteling, gevoelloosheid en spierswakheid (veral in die onderste deel van u liggaam) wanneer u 'n spinale punksie of spinale narkose gehad het
- u enige bloeding het wat nie vanself stop nie
- indien u enige teken het van verstopping van 'n bloedvat deur 'n bloedklont soos:
    - krampende pyn, rooiheid, warmte of swelling in een van u bene – dit is simptome van diep-aarse trombose
    - asemloosheid, pyn op die bors, flou word of bloed hoes – dit is simptome van 'n pulmonale embolus
- indien u 'n pynlike uitslag van donkerrooi kolle onder die vel het wat nie weggaan wanneer u druk daarop plaas nie
- u tekens toon van te veel bloeding soos om baie swak, moeg, bleek of duiselig te wees met hoofpyn of onverklaarbare swelling.

U dokter kan u versoek om 'n bloedtoets te laat doen om u bloedplaatjietelling na te gaan.

Dit is alles ernstige newe-effekte. U benodig dalk dringende mediese hulp.

Lig u dokter in indien u enige van die volgende opmerk:

Algemene newe-effekte

- hoofpyn
- toename in lewerensieme

- jeukende rooi vel
- galbulte, urtikaria
- kneusing of pyn by die inspuitplek
- u makliker kneus as gewoonlik – dit kan wees as gevolg van 'n bloedprobleem met lae bloedplaatjietellings
- hoë bloedplaatjietellings in die bloed
- verlaagde rooibloedseltelling
- skielike erge hoofpyn – dit kan 'n teken wees van bloeding in die brein
- 'n gevoel van teerheid en swelling in u maag – u mag dalk bloeding in u maag hê
- bloeding by wonde
- neusbloeding
- bloed in urien.

Minder algemene newe-effekte:

- 'n toename in die aantal eosinofiele in u bloed – u dokter sal dit kan kontroleer deur 'n bloedtoets uit te voer
- vergeling van u vel of oë en u urien word donkerder van kleur – dit kan 'n lewerprobleem aandui
- haarverlies
- groot rooi onreëlmatige velletsels met of sonder blase
- perserige kneusplekke onder die vel
- inflammasie en weefselskade (nekrose) van bloedvatwande (lumen) en geassosieerde vel
- osteoporose ('n toestand waar u bene meer geneig is om te breek) na langtermyn gebruik
- harde knop of klont by die inspuitplek
- vel irritasie (lokale irritasie)
- verhoogde kalium in u bloed. U dokter sal dit kan kontroleer deur 'n bloedtoets uit te voer.

Indien u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, stel u dokter of apteker asseblief in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, lig u dokter, apteker of verpleër in. U kan ook newe-effekte by SAHPRA aanmeld via die vorm **"6.04 Adverse Drug Reaction Reporting Form",** wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **CRUSIA** te verskaf.

5. Hoe om CRUSIA te bêre

- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 25 °C. Moenie vries nie.
- Moenie hierdie medisyne gebruik as u skade aan die inspuiting, deeltjies in die oplossing of 'n abnormale kleur van die oplossing opmerk nie (sien **Hoe CRUSIA lyk en die inhoud van die verpakking**).
- Moet nie hierdie medisyne gebruik na die vervaldatum wat op die karton en die flessie na "EXP" aangedui word nie. Die vervaldatum verwys na die laaste dag van daardie maand.
- Neem alle ongebruikte medisyne terug na u apteker toe.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat CRUSIA bevat

Die aktiewe bestanddeel is enoksapariennatrium.

Elke mL bevat 100 mg enoksapariennatrium, gelykstaande aan 10 000 IE anti-Xa-aktiwiteit.

CRUSIA 20: Elke voorafgevulde spuit van 0,2 mL bevat 2 000 IE (20 mg) enoksapariennatrium.

CRUSIA 40: Elke voorafgevulde spuit van 0,4 mL bevat 4 000 IE (40 mg) enoksapariennatrium.

CRUSIA 60: Elke voorafgevulde spuit van 0,6 mL bevat 6 000 IE (60 mg) enoksapariennatrium.

CRUSIA 80: Elke voorafgevulde spuit van 0,8 mL bevat 8 000 IE (80 mg) enoksapariennatrium.

CRUSIA 100: Elke voorafgevulde spuit van 1 mL bevat 10 000 IE (100 mg) enoksapariennatrium.

Die ander bestanddeel is water vir inspuitings.

Hoe CRUSIA lyk en die inhoud van die verpakking

CRUSIA is 'n helder, steriele oplossing, vry van sigbare deeltjies.

CRUSIA is verpak in helder, deursigtige tipe I-glas voorafgevulde spuite met swart chloorbutiel rubberstopper toegerus met ‘n inspuitnaald met of sonder 'n outomatiese veiligheidstoestel vir sommige aanbiedings.

Die naaldskerm is gemaak van sintetiese rubber en 'n stewige bedekking van polipropileen.

Voorafgevulde spuite word in plastiek bakkies en kartonhouers gestoor.

CRUSIA 20: 0,2 mL oplossing vir inspuiting in 'n 0,5 mL voorafgevulde spuit sonder afmerkings. Verpakkingsgroottes van 2, 10 en 50 spuite.

CRUSIA 40: 0,4 mL oplossing vir inspuiting in 'n 0,5 mL voorafgevulde spuit sonder afmerkings. Verpakkingsgroottes van 2, 10, 30 en 50 spuite.

CRUSIA 60: 0,6 mL oplossing vir inspuiting in 'n 1,0 mL afgemerkte voorafgevulde spuit. Verpakkingsgroottes van 2, 10 en 30 spuite.

CRUSIA 80: 0,8 mL oplossing vir inspuiting in 'n 1,0 mL afgemerkte voorafgevulde spuit. Verpakkingsgroottes van 2, 10 en 30 spuite.

CRUSIA 100: 1,0 mL oplossing vir inspuiting in 'n 1,0 mL afgemerkte voorafgevulde spuit. Verpakkingsgroottes van 2, 10 en 30 spuite.

Nie alle verpakkingsgroottes word moontlik bemark nie.

Houer van Sertifikaat van Registrasie

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2013

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Hierdie voubiljet is mees onlangs hersien in

13 Maart 2023

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CRUSIA 40: 55/8.2/0010

CRUSIA 60: 55/8.2/0011

CRUSIA 80: 55/8.2/0012

CRUSIA 100: 55/8.2/0013

PIL 13 March 2023