Exarane/Exarane Forte

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Exarane?

Exarane* contains the active ingredient enoxaparin sodium. Exarane is used to prevent clots from getting bigger or stopping new clots from forming following hospital procedures or illness. Exarane is also used to treat DVT and heart problems including unstable angina and heart attack when taken with aspirin. Exarane is used to stop blood clots forming in the tubes of your kidney dialysis machine.

For more information, see Section 1. Why am I using Exarane? In the full CMI.

2. What should I know before I use Exarane?

Do not use if you have ever had an allergic reaction to Exarane, heparin or any medicine derived from heparin, or any of the ingredients listed at the end of the CMI. Do not take Exarane if you have or have had major bleeding disorders, injury to the brain, stomach or bowel problems, or bacterial infections of the heart.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Exarane? In the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Exarane and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? In the full CMI.

4. How do I use Exarane?

- Your doctor will decide what dose you will receive.
- Exarane is usually administered by injection under the skin. It can also be injected into the tubing of a dialysis machine or into a vein by a doctor or nurse.

More instructions can be found in Section 4. How do I use Exarane? in the full CMI.

5. What should I know while using Exarane?

Things you	Remind any doctor, dentist, or pharmacist you visit that you are using Exarane.	
should do	Tell your doctor if you become pregnant.	
	Tell your doctor if you have an artificial heart valve.	
	• Tell your doctor you are using Exarane if you will be having a spinal or epidural injection for anaesthesia.	
Things you	Do not stop using this medicine without checking with your doctor.	
should not do	Do not mix Exarane with other injections or fluids.	
	• Do not inject Exarane into a muscle.	
Looking after	• Store below 25°C. Do not freeze. Store in a cool dry place away from moisture, heat, or sunlight.	
your medicine	• Keep the syringe in the pack until it is time to use it.	

For more information, see Section 5. What should I know while using Exarane? in the full CMI.

6. Are there any side effects?

Less serious side effects include pain, bruising, bleeding, swelling, itch, or rash at the injection site. Serious side effects include allergic reactions, signs of abnormal bleeding such as prolonged bleeding or bruising easily, nausea, gut pain, or numbness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Exarane/Exarane Forte

Active ingredient(s): enoxaparin sodium

Consumer Medicine Information (CMI)

This leaflet provides important information about using Exarane. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Exarane.

Where to find information in this leaflet:

- 1. Why am I using Exarane?
- 2. What should I know before I use Exarane?
- 3. What if I am taking other medicines?
- 4. How do I use Exarane?
- 5. What should I know while using Exarane?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Exarane?

Exarane contains the active ingredient enoxaparin sodium. Exarane is an anticoagulant that belongs to a group of medicines called Low Molecular Weight Heparin (LMWH). These medicines help to prevent clots from getting bigger and stopping new clots from forming.

Exarane is used to prevent clotting following hospital procedures or illness.

Exarane is also used to treat deep vein thrombosis and heart problems including unstable angina and heart attack when taken with aspirin.

Exarane is used to stop blood clots forming in the tubes of your kidney dialysis machine.

2. What should I know before I use Exarane?

Warnings

Do not use Exarane if:

- you are allergic to enoxaparin sodium, heparin or any other medicines derived from heparin, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- you have, or have ever had any of the following medical conditions:
 - major bleeding disorders
 - certain types of injury to the brain including stroke
 - stomach or bowel problems, such as ulcers or ulcerative colitis

bacterial infections in your heart

Check with your doctor if you:

- have or have had any of the following medical conditions:
 - major bleeding disorder or blood clotting problem including recent stroke or hereditary blood disorders
 - bacterial endocarditis, an inflammation of the lining of the heart caused by bacteria
 - an artificial heart valve particularly in women who are pregnant
 - uncontrolled high blood pressure
 - stomach or bowel problems such as ulcers or ulcerative colitis
 - kidney disease
 - liver disease
 - diabetes
 - eye disease related to diabetes
 - o recent surgery on the brain, spine, or eye
 - spinal surgery or spinal deformity
 - o underweight or overweight
 - o high level of potassium in your blood
- take any medicines for any other condition

If your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection), tell your doctor you are using Exarane.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Exarane is not recommended while you are breastfeeding.

Children

Do not give Exarane to a child.

3. What if I am taking other medicines?

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

Some medicines may interfere with Exarane and affect how it works such as:

- medicines used to prevent or treat blood clots, such as clopidogrel or ticlopidine
- medicines containing aspirin or salicylates
- Dextran 40, a medicine used to treat shock
- medicines used to treat inflammatory disease, such as non-steroidal inflammatory drugs, such as ibuprofen or diclofenac, or steroids such as prednisolone
- medicines which increase the level of potassium in the blood, such as potassium salts, fluid tablets and some medicines for heart problems

Your doctor will monitor your potassium levels and your ability to form blood clots if you are using any of these medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Exarane.

4. How do I use Exarane?

How much to use and when to use Exarane

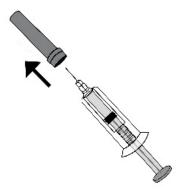
- Your doctor will decide what dose you will receive.
- Exarane is usually administered by injection under the skin.
- Follow the instructions provided and use Exarane until your doctor tells you to stop.

<u>Instructions on injecting yourself with Exarane (Safety Lock System):</u>

- Wash your hands and the area that you will inject with soap and water. Dry them.
- Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. In a lounge chair, recliner, or propped up in bed with pillows is ideal.
- 3. Choose an area on the right or left side of your stomach. This should be at least 5 cm 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 were last injected.

- Remove the plastic blister containing the prefilled syringe from the box. Open the blister and remove the pre-filled syringe.
- 5. Carefully pull off the needle cap from the syringe. Throw away the cap. The syringe is pre-filled and ready to use.

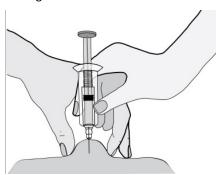


Do not press on the plunger before injecting yourself. Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile)

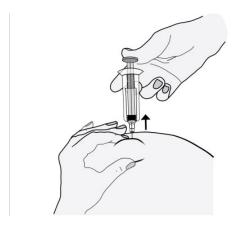
 Hold the syringe in the hand you write with (like a pencil) and with your other hand, gently pinch the cleaned area of your abdomen between your forefinger and thumb to make a fold in the skin.

Make sure you hold the skin fold throughout the injection.

7. Hold the syringe so that the needle is pointing downwards (vertically at a 90 º angle). Insert the full length of the needle into the skin fold.



- 8. Press down on the plunger with your thumb. This will inject the medicine into the fatty tissue of the abdomen. Make sure you hold the skin fold throughout the injection.
- 9. Remove the needle by pulling it straight out. Do not release the pressure on the plunger.



10. To avoid bruising, do not rub the injection site after you have injected yourself.

 Push hard the plunger. The needle guard, which is in the form of a plastic cylinder, will be activated automatically and it will completely cover the needle.



12. Drop the used syringe into the sharps container. Close the container lid tightly and place the container out of reach of children.

For the prevention of blood clots

The usual dose for moderate risk patients is 20 mg once per day.

The usual dose for high risk patients is 40 mg once per day.

For the treatment of bloods clots in the leg or deep vein

The usual dose is 1 mg per kg of body weight twice per day or 1.5 mg per kg of body weight once per day.

Warfarin is usually started within 3 days of using Exarane.

For patients requiring dialysis

The usual dose is 1 mg per kg of body weight into the tubing of the dialysis machine at the start of the session.

Additional doses may be needed.

For patients who have had severe heart attacks

The usual dose is:

- 30 mg injected into the vein and 1 mg per kg of body weight injected under the skin, then
- 1 mg per kg of body weight twice per day.

For patients with other types of heart disease

The usual dose is 1 mg per kg of body weight twice per day. Your doctor may change this dose as needed.

How to use Exarane

- Exarane may be given by your doctor, nurse, or you.
- Exarane is usually given by injection under the skin or into the tubing of a dialysis machine. It can also be given by injection into a vein. This will be done in hospital by a doctor or nurse.

Prefilled syringes

The prefilled syringes are ready to use. The air bubble in syringe should not be expelled.

Graduated Prefilled Syringes

The graduated syringes have markings indicating the volume in the syringe. The volume (mL) or mass (mg) to be injected should be precisely measured according to the dosage recommended by your doctor.

Injection Technique

- The recommended site for injection is the stomach area. A different injection site should be used for each injection.
- The needle on the prefilled syringe is covered in a silicon coating. Do not wipe the needle or allow the solution to crystallise on the needle as this will damage the coating.
- Gently fold the skin using a thumb and finger. Hold the fold of the skin for the duration of the injection.
- Introduce the whole length of the needle vertically into the thickness of the skin fold and inject Exarane.
- Do not rub the injection site after administration.
- Exarane is for single use only. Use only once and discard after use.

If you use too much Exarane

If you think that you have used too much Exarane or have been given too much Exarane, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13
 11 26 if you are in Australia), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Exarane?

Things you should do

If you are about to be started on a new medicine tell your doctor, dentist, or pharmacist that you are using Exarane.

Tell your doctor immediately if you become pregnant.

Tell your doctor if you have an artificial heart valve.

If you plan to have surgery tell your doctor or dentist that you are using Exarane.

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

Ask your doctor are there any activities, such as sports, you should avoid while using Exarane.

Tell your doctor if you experience any significant loss of weight or increase in weight.

Keep all your appointments with your doctor and any blood tests.

Remind any doctor, dentist or pharmacist you visit that you are using Exarane.

Exarane is not interchangeable with other medicines containing low molecular weight heparin medicines.

Things you should not do

- Do not give Exarane to anyone else even if they have the same condition as you.
- Do not use Exarane to treat any other complaints unless a doctor tells you to.
- Do not stop using Exarane or change the dosage without checking with your doctor.
- Do not mix Exarane with other injections or infusion fluids. Certain medicines or solutions contain ingredients that could interact with Exarane.
- Do not inject Exarane into a muscle.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Exarane affects you.

Looking after your medicine

Store below 25°C

- Do not freeze Exarane
- Keep the syringes in the pack until it is time to use them

Product is for single use in one patient only.

Discard any residue. Contains no antimicrobial agent.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Injection site-related Pain, bruising or irritation Hard, inflamed nodules Itchy, red rash Bleeding 	Speak to your doctor if you have any of these less

•	Itchy skin	serious side
		effects and
		they worry you.

Serious side effects				
Serious side effects	What to do			
Allergy-related	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.			
 Difficulty in breathing, symptoms of hayfever, feeling faint, itching hives, blisters, or other symptoms of allergy 				
Injection site-related				
• Painful itchy red/purple rash				
Bleeding-related				
Bleeding, including nose bleeds or prolonged bleeding from cuts				
Bruising more easily than normal	These side			
• Red or dark brown urine, red or black bowel motions	effects are rare.			
• A fine widespread rash, especially noticeable on your mouth or eyes or sudden onset of white or blue colour in fingers in toes suggesting poor blood supply.				
Spinal or epidural injection related				
• Pain in the middle of your back				
Numbness and weakness in your legs				
• Gut problems				
Problems passing urine				
Other				
• Nausea, diarrhoea, fever				
• Swelling of the hands, ankles, or feet.				
• Severe abdominal pain, chest pain and headache				
 Numbness (paralysis), problems with coordination, dizziness, tiredness, lightheadedness, 				

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

· Blurred vision, confusion or

difficulty speaking

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Exarane contains

Active ingredient	enoxaparin sodium
(main ingredient)	
Other ingredients	water for injections
(inactive ingredients)	It also contains materials of porcine (pig) origin.
Potential allergens	enoxaparin sodium

Do not take this medicine if you are allergic to any of these ingredients.

What Exarane looks like

Exarane is clear, colourless to pale yellow solution for injection.

The following syringes are registered:

Exarane (with safety lock system)

Ready-to-use, prefilled syringes

- 20 mg of enoxaparin sodium per 0.2 mL (pack of 10);
 AUST R 429094
- 40 mg of enoxaparin sodium per 0.4 mL (pack of 10);
 AUST R 429090

Ready to use Prefilled Syringes with graduated markings

- 20 mg of enoxaparin sodium per 0.2 mL (pack of 10); AUST R 429094
- 40 mg of enoxaparin sodium per 0.4 mL (pack of 10); AUST R 429090
- 60 mg of enoxaparin sodium per 0.6 mL (pack of 10);
 AUST R 429095
- 80 mg of enoxaparin sodium per 0.8 mL (pack of 10);
 AUST R 429093
- 100 mg of enoxaparin sodium per 1.0 mL (pack of 10);
 AUST R 429091

Exarane Forte (with safety lock system)

Ready to use Prefilled Syringes with graduated markings

- 120 mg of enoxaparin sodium per 0.8 mL (pack of 10); AUST R 429092
- 150 mg of enoxaparin sodium per 1.0 mL (pack of 10); AUST R 429096

Who distributes Exarane/Exarane Forte

Juno Pharmaceuticals Pty Ltd, 15-17 Chapel St Cremorne Vic 3121 www.junopharm.com.au

This leaflet was prepared in July 2024.

*References to "Exarane" refer to both Exarane and Exarane Forte.