Danaparoid Sodium
750 anti-Xa units, solution for injection

Danaparoid sodium

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Read all of this leaflet carefully before you are given this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Danaparoid Sodium is and what it is used for

Danaparoid sodium, the active ingredient in Danaparoid Sodium, is a medicine that prevents blood from clotting (anticoagulant), and belongs to a group of medicines called heparinoids.
Danaparoid Sodium prevents the formation of blood clots in blood vessels, and is used in patients who have an increased risk of blood clot formation, and in patients who are allergic to another medicine called heparin.
You should ask your doctor if you are unsure why you have been given Danaparoid Sodium.

2. Before you are given Danaparoid Sodium

You should not be given Danaparoid Sodium if:
- you are allergic (hypersensitive) to danaparoid sodium, or any of the other ingredients of Danaparoid Sodium.
- you are being treated for blood clots, and are having a spinal or epidural anaesthetic
- you are prone to bleeding easily, unless you cannot be given heparin
- you have an ulcer, unless the ulcer is the reason for your operation
- have had a stroke
- are bleeding and it can't be stopped
- you have severe kidney or severe liver disease, unless you cannot be given heparin

• have very high blood pressure
• have damage to the retina of the eye due to diabetes
• have an infection of the inner lining and valves of the heart (acute bacterial endocarditis).
• previous treatment with heparins (a group of medicines often used to treat blood clots) caused a large drop in the number of a type of blood cell called platelets, and if a blood test showed that this may happen with Danaparoid Sodium

Take special care with Danaparoid Sodium
Medicines are not always suitable for everyone.
→ Tell your doctor before you are given Danaparoid Sodium if you suffer from or have suffered in the past from any of the following conditions, as extra supervision may be necessary:
• kidney or liver disease
• have an active stomach ulcer
• a history of asthma or allergy
as this medicine contains sodium sulphite (see Important Information about some of the Ingredients of Danaparoid Sodium, below).

Taking other medicines
Some medicines can affect the way Danaparoid Sodium works, or Danaparoid Sodium itself can affect how other medicines taken at the same time work. These include:
• oral anticoagulants (medicines used to stop blood clots)
• aspirin or anti-rheumatics
• steroids.
→ Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and Breast-feeding
If you are pregnant, or suspect that you are pregnant or if you are breast-feeding then tell your doctor. Your doctor will decide whether Danaparoid Sodium can be given to you. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Danaparoid Sodium is not known to have any effects on the ability to drive, or use machinery.

Important information about some of the ingredients of Danaparoid Sodium
This medicine contains less than 1 mmol sodium (23mg) per dose - that is essentially ‘sodium free’.
• Danaparoid Sodium contains sodium sulphite which may rarely cause severe hypersensitivity reactions and a difficulty in breathing (bronchospasm).
Symptoms include: tightening of the chest, swelling, itching or rash.
Please see section 6 for a full list of ingredients.

3. How Danaparoid Sodium is given

Adults and elderly
The medicine is given as an injection under the skin or as an infusion (a slow injection) by your doctor or nurse.
The normal dose is 750 units, twice-a-day, for 7 to 10 days.
Higher doses may be necessary in some patients.

Children
Danaparoid Sodium can be used in children, but the doctor will decide the dose as experience is limited.

If you are given more Danaparoid Sodium than you should
Danaparoid Sodium will be given to you by a doctor or nurse so you are unlikely to be given too much medicine. However, if too much Danaparoid Sodium is given you may bleed too much. This may be shown by:
- nosebleeds, bleeding gums;
- blackened stools (may indicate blood loss from stomach or intestines);
- blood in the urine;
- unusually severe periods in women.

→ If you have any of these symptoms or you think you have been given too much Danaparoid Sodium, tell your doctor immediately.
If you have any further questions about being given Danaparoid Sodium, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, Danaparoid Sodium can cause side effects, although not everybody gets them.
→Tell your doctor immediately if you experience any of the following symptoms after being given this medicine together with a spinal or epidural anaesthetic. Although they are very rare, these symptoms can be serious.
• back pain
• tingling, numbness or weakness in the legs
• bowel or bladder problems.

Common side effects
(affect up to 1 in 10 people)
• a large drop in the number of cells that clot the blood (thrombocytopenia) in patients already hypersensitive to heparin
• increased bleeding after the operation
• skin rash

Uncommon side effects
(affect up to 1 in 100 people)
• bruises and/or pain around the injection site
• allergic reaction to Danaparoid Sodium.

This may cause sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)

Rare side effects
(affect up to 1 in 1000 people)
• increased bleeding or swelling containing blood at the operation site (haematoma);

Very rare side effects
(affect up to 1 in 10000 people)
When Danaparoid Sodium is used at the same time as a spinal or epidural anaesthetic, bruising of the spine may occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. How to store Danaparoid Sodium
Keep out of the reach and sight of children.
Do not store above 30 ºC.
Do not freeze.
Keep the ampoules in the outer carton to protect from light.
Do not use Danaparoid Sodium after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

6. Further information

What Danaparoid Sodium contains
Each 1ml glass ampoule contains 750 anti-factor Xa units (0.6ml) of the active ingredient danaparoid sodium, corresponding to 1250 anti-factor Xa units per ml.
The other ingredients are:
Sodium sulphite, Sodium chloride, Hydrochloric acid, Water

What Danaparoid Sodium looks like and contents of the pack
Danaparoid Sodium comes in glass ampoules. It is a solution for injection. Each ampoule of Danaparoid Sodium contains 0.6ml of medicine, and is available in packs of 10 or 20 ampoules.

More about Danaparoid Sodium
Danaparoid Sodium contains a natural substance, derived from pig intestine, which prevents the formation of blood clots in blood vessels (thrombosis).
Blood clots which form in veins may restrict the blood flow causing tissue to die. Small parts of the clot can break off and may block the blood circulation in the lungs. A blood clot in the lungs may be very serious.
Patients who are bedridden have an increased risk of clot formation in the veins of the legs, especially if they have undergone an operation. These patients receive Danaparoid Sodium to prevent the formation of blood clots.

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0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name: Danaparoid Sodium

Reference Number:
PL 46302/0228 This is a service provided by the Royal National Institute for Blind People

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