Package leaflet: Information for the user

Danaparoid Sodium 750 anti-Xa units, solution for injection
Danaparoid sodium

Read all of this leaflet carefully before you are start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is 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. What you need to know before you use Danaparoid Sodium

Do not use Danaparoid Sodium:
- if you are allergic to danaparoid sodium, or any of the other ingredients of this medicine (listed in section 6);
- if you had a haemorrhagic stroke (due to a bleed in the brain) in the last three months;
- if you are bleeding and it can't be stopped;
- if you have very high blood pressure that cannot be controlled;
- if you have damage to the retina of the eye due to diabetes;
- if you have an infection of the inner lining and valves of the heart (acute bacterial endocarditis);
- if you are using danaparoid to treat blood clots in your body and going to receive spinal or epidural anaesthesia or lumbar puncture within 24 hours.

Warnings and precautions
Talk to your doctor before using Danaparoid Sodium if you have or ever have had any of the following conditions, as extra supervision may be necessary:

- you have a tendency to bleeding severely, for example, haemophilia, or an increased bleeding risk
- kidney or liver disease
- if you have an ulcer(s) in the stomach or small intestine
- if you are allergic to **sulphite**, as this can cause severe allergic reactions and breathing difficulties in asthma patients.
- if you ever had a **diagnosis** of **heparin-induced thrombocytopenia** (**HIT**)
- if 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
- if a spinal or epidural anaesthetic is necessary; extra supervision may be needed

Children and adolescents
There is limited experience with Danaparoid Sodium in children and adolescents.

Other medicines and Danaparoid Sodium
Tell your doctor or pharmacist if you are taking, have recently taken or might take any 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.

Medicines which may increase the risk of bleedings when taken at the same time as Danaparoid Sodium include:
- medicines used to **prevent blood clots** like *Vitamin K Antagonist*, for example, warfarin;
- medicines used to **dissolve blood clots**, for example, alteplase;
- *aspirin* and other **anti-inflammatory drugs** (like *NSAIDs*), for example, for treatment of rheumatic disorders
- medicines that may cause ulcers (such as *corticosteroids*).

Pregnancy, breast-feeding and fertility
Pregnancy and breast-feeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Danaparoid Sodium may be used while breast-feeding if alternative treatments are unacceptable for medical reasons.

Fertility
There is no available information on effect of Danaparoid Sodium on fertility.

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

Danaparoid Sodium contains 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.

3. How to use Danaparoid Sodium

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

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 use more Danaparoid Sodium than you should
Danaparoid Sodium will be given to you by a doctor or a 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 show 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 on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When a heparin (an antithrombotic) is used at the same time as a spinal or epidural anaesthetic, bruising of the spine may occur. This occurs very rarely (see Section 2).

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: may 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: may 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: may affect up to 1 in 1000 people
- increased bleeding or swelling containing blood at the operation site (haematoma).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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 in order 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. Content of the pack and other 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 and water for injections.

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.

Marketing Authorisation Holder
Mylan Products Ltd.
20 Station Close,
Potters Bar, Herts,
EN6 1TL,
United Kingdom

Manufacturer
FAMAR Health Care Services Madrid, S.A.U
Avda. Leganés, 62,
Alcorcón 28923
Madrid,
Spain

And

Aspen Bad Oldesloe GmbH
Industiestraβe 32-36
23843 Bad Oldesloe
Germany

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Other sources of information
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
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