1. NAME OF THE MEDICINAL PRODUCT

Danaparoid sodium 750 anti-Xa units/0.6 ml, solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Danaparoid sodium 750 anti-Xa units/0.6 ml, solution for injection contains danaparoid sodium, which is a non-heparin mixture of low molecular weight sulphated glycosaminoglycuronans derived from animal mucosa. The mixture comprises heparan sulphate, dermatan sulphate and a minor amount of chondroitin sulphates.

One ampoule (0.6mL) contains 750 anti-factor Xa units danaparoid sodium corresponding to 1250 anti-factor Xa units per mL. The anti-Xa unit is derived from the international heparin standard in an antithrombin containing buffer system.

Excipients with known effect:
sodium chloride and sodium sulphite.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear/colourless to pale yellow aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Prevention of deep vein thrombosis and its possible consequences in patients undergoing general or orthopaedic surgery.
- Treatment of thrombo-embolic disorders in patients who require urgent parenteral anti-coagulation because of the development or history of heparin-induced thrombocytopenia (HIT).

4.2 Posology and method of administration

a) Non-HIT patients (DVT prophylaxis)

- In general, danaparoid sodium should be administered by subcutaneous injection at a dose of 750 U for patients ≤90 kg body weight, twice daily for a period of maximally 14 days unless it is required longer in patients for whom there is no reasonable antithrombotic alternative.
- For patients > 90 kg body weight, a dose of 750 U three times a day or 1250 U twice a day is recommended.
- In surgical patients it is recommended to start this dosing pre-operatively and to give the last pre-operative dose 1-4 hours before surgery.

Monitoring
Plasma anti-Xa activity is linearly related to the dose of danaparoid sodium given. In general, monitoring of plasma anti-Xa activity is not necessary. If monitoring of anticoagulant activity is performed then a functional anti-factor Xa test using a chromogenic peptide substrate should be used. In this test danaparoid sodium should be used as standard for constructing the reference curve.

Renal impairment and patients >90kg
In patients suffering from renal insufficiency and/or patients > 90kg body weight monitoring, once or twice a week during routine subcutaneous therapy, (using an amidolytic assay) is recommended to check for drug accumulation or underdosing, respectively.

b) HIT patients
The diagnosis of HIT should as a minimum be based on:

1) thrombocytopenia (platelet count<100x10^9/L) occurring during heparin administration and
2) exclusion of all other causes of thrombocytopenia

In general monitoring of plasma anti-Xa activity is not necessary. However, in patients suffering from renal insufficiency and/or patients weighing over 90kg, monitoring (using an amidolytic assay) is recommended.
Danaparoid Sodium should be administered intravenously as a bolus of 2500 anti-Xa units (for patients less than 55kg 1250 units, if over 90kg, 3750 units) followed by an intravenous infusion of 400units/h for 2 hours, then 300 units/h for 2 hours, then a maintenance infusion of 200 units/h for 5 days. The expected plasma anti-Xa levels are 0.5-0.7 units/ml 5-10 minutes after the bolus, not higher than 1.0 units/ml during the adjustment phase of maintenance infusion and 0.5-0.8 units/ml during the maintenance infusion.

Dosage in the elderly:
Clearance of anti-factor Xa activity has not been shown to be markedly reduced in the elderly and the usual dosage is recommended.

Children:
There is insufficient experience with the use of Danaparoid Sodium in children to suggest a dosage regimen for this group of patients.

Dosage in patients with moderately impaired renal and/or liver function:
Danaparoid Sodium should be used with caution in patients with moderately impaired renal and/or liver function with impaired haemostasis.

Conversion to anticoagulants is possible, however it is advisable only to start such a therapy once there is adequate antithrombotic control with Danaparoid Sodium. Oral anticoagulants can be given with the infusion (maximum rate 300units/h) which can then be stopped when the international normalised ratio is ≥1.5. If the bleeding risk is high then either:

(a) stop the infusion and start Danaparoid Sodium 750 anti-Xa units/0.6 ml subcutaneously twice a day, then 24 hours later start anticoagulants 48-72 hours before Danaparoid Sodium is withdrawn to give time for the prothrombin time, Thrombotest and international normalised ratio to reach therapeutic levels (measurement of these parameters is not reliable within 5 hours of Danaparoid Sodium injection (See "Interactions with other medicaments and other forms of interactions")) or
(b) stop the infusion, give no further Danaparoid Sodium then start the anticoagulants 12 hours later.

4.3 Contraindications

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- spinal or epidural anaesthesia or loco-regional anaesthesia when danaparoid sodium is used for treatment in the previous 24 hours (see section 4.4)
- severe haemorrhagic diathesis, e.g. haemophilia and idiopathic thrombocytopenic purpura, unless the patient also has HIT and no alternative anti-thrombotic treatment is available
- haemorrhagic cerebrovascular accident within the previous three months
- uncontrollable active bleeding state
- severe renal- and/or hepatic insufficiency, unless the patient also has HIT and no alternative anti-thrombotic treatment is available
- severe uncontrolled hypertension
- active gastroduodenal ulcer, unless it is the reason for operation
- diabetic retinopathy
- acute bacterial endocarditis
- hypersensitivity to sulphite

4.4 Special warnings and precautions for use

Danaparoid sodium cross-reactivity
The incidence of serological cross-reactivity of Danaparoid Sodium with the heparin-induced antibody before the start of therapy is approximately 5%; however, one of the main causes of pre-treatment danaparoid cross-reactivity appears to be due to residual heparin in the circulation as a result of a prior heparin administration. The incidence of clinical cross-reactivity developing during danaparoid sodium therapy is approximately 3% and many of these patients had a negative pre-treatment serological cross-reactivity test. Although the risk of antibody-induced thrombocytopenia and thrombosis during danaparoid sodium therapy (i.e. clinical cross-reactivity) is very small, it is advisable to check the number of platelets daily during the first week of treatment, on alternate days during the second and third weeks, and weekly to monthly thereafter. If a pre-treatment cross-reactivity test with danaparoid sodium is positive but it is decided to use danaparoid sodium, then the number of platelets should be checked daily until danaparoid sodium treatment is stopped. If antibody-induced thrombocytopenia occurs, one should stop the use of danaparoid sodium and consider alternative treatment.

Increased risk of haemorrhage
Danaparoid sodium should not be administered to patients with severe haemorrhagic diathesis, e.g. haemophilia and idiopathic thrombocytopenic purpura, unless the patient also has HIT and no suitable alternative antithrombotic treatment is available.

Danaparoid sodium should not be used in patients with severe renal and hepatic insufficiency unless the patient also has HIT and no alternative antithrombotic treatment is available.

Danaparoid sodium should be used with caution in patients with moderately impaired renal, and/or liver function with impaired haemostasis, ulcerative lesions of the gastro-intestinal tract or other diseases which may lead to an increased danger of haemorrhage into a vital organ or site.

Danaparoid sodium should not be administered to patients with active gastric or duodenal ulceration, unless it is the reason for operation.

Since severe bleeding may occur post-operatively in HIT patients undergoing a cardiopulmonary bypass procedure, danaparoid sodium is not recommended during the procedure, unless no other antithrombotic treatment is available (see Section 4.2 *Special Populations*).

Immediate hypersensitivity reactions
Danaparoid sodium contains sodium sulphite. In asthma patients hypersensitive to sulphite the latter can result in bronchospasm and/or anaphylactic shock.

Risk of bleeding with spinal/epidural anaesthesia/spinal lumbar puncture
Spinal/epidural anaesthesia or lumbar puncture must not be performed within 24 hours of administration of danaparoid sodium (see also section 4.3). As with heparins, in patients undergoing peridural or spinal anaesthesia or spinal puncture, the prophylactic use of danaparoid sodium may theoretically be associated with epidural or spinal haematoma resulting in prolonged or permanent paralysis. The risk is increased by the prolonged use of a peridural or spinal catheter for anaesthesia or analgesia, by the concomitant use of drugs affecting haemostasis such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors or anticoagulants, and by traumatic or repeated puncture. In decision-making on the interval between the last administration of danaparoid sodium at prophylactic doses and the placement or removal of a peridural or spinal catheter, the product characteristics and whether or not the spinal tap was traumatic or had to be repeated, as well as the patient profile should be taken into account. Subsequent dose should not take place before at least four hours have elapsed. Re-administration should be delayed until the surgical procedure is completed.

Should a physician decide to administer Danaparoid Sodium in the context of peridural or spinal anaesthesia, extreme vigilance and frequent monitoring must be exercised to detect any signs and symptoms of neurologic impairment, such as back pain, sensory and motor deficits (numbness and weakness in lower limbs) and bowel or bladder dysfunction. Nurses should be trained to detect such signs and symptoms. Patients should be instructed to inform immediately a nurse or a clinician if they experience any of these.

If signs or symptoms of epidural or spinal haematoma are suspected, urgent diagnosis and treatment including spinal cord decompression should be initiated. Danaparoid Sodium should not be given by the intramuscular route. The safety and efficacy of danaparoid sodium in patients with non-haemorrhagic stroke remains to be confirmed.

No incidences of osteoporosis have been reported in patients treated with the recommended dose of danaparoid sodium. However, as for heparin, treatment with glycosaminoglycuronan may result in osteoporosis if the dosage is inappropriate.
It should be noted that the anti-Xa units of Danaparoid Sodium have a different relationship to clinical efficacy than those of heparin and low molecular weight heparins.

4.5 Interactions with other medicinal products and other forms of interaction

In clinical studies no clinically significant interactions with other medications have been found. Danaparoid sodium may be used together with oral anticoagulants vitamin K antagonists (VKA), drugs which interfere with platelet function (such as aspirin and non-steroidal anti-inflammatory drugs) or potentially ulcerogenic drugs (such as corticosteroids), but caution remains necessary this is particularly important in patients undergoing peridural or spinal anaesthesia or spinal puncture (see section 4.4.). Monitoring of anticoagulant activity of oral anticoagulants by prothrombin

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 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

time and thrombotest is unreliable within 5 hours after danaparoid sodium administration.
Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is a limited amount of data with the use of danaparoid sodium during pregnancy. Case reports indicate no harmful effects.
In the limited number of umbilical cord blood samples checked after delivery, there was no evidence of anti-Xa activity due to danaparoid sodium.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).
Danaparoid sodium is not recommended for general use in pregnancy.

Breast-feeding
Breast milk samples tested for anti-Xa activity showed no or negligible amounts of anti-Xa activity (which would be hydrolysed in the infant's stomach and rendered harmless).

Fertility
There is no data available on the effect of danaparoid sodium on human fertility.

4.7 Effects on ability to drive and use machines

Danaparoid sodium is not known to have any effect on the ability to drive and use machines.

4.8 Undesirable effects

Danaparoid sodium has the potential to increase the risk of bleeding.

The following convention has been used for the classification of adverse reactions in terms of frequency:
Very common ≥1/10
Common ≥1/100 to < 1/10
Uncommon ≥1/1,000 to <1/100
Rare ≥1/10,000 to <1/1,000
Very rare <1/10,000
Not known (cannot be estimated from the available data)

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

	Common	Uncommon	Rare
Blood and the lymphatic system disorders	thrombocytopenia*, heparin-induced thrombocytopenia		immune thrombocytopenic purpura
Immune system disorders		hypersensitivity, drug hypersensitivity	
Skin and subcutaneous tissue disorders	rash	purpura, rash maculo-papular, rash erythematous, pruritus, urticaria	rash generalised, rash maculovesicular, injection site rash, infusion site rash, rash macular
General disorders and administration site conditions		Injection site reaction	Injection (inj.) site: - haemorrhage - discomfort - hypersensitivity - irritation - coldness - pruritus inj. **or** infusion site: - erythema - pain - swelling - warmth infusion site: - bruising - reaction
Injury, poisoning and procedural complications	post procedural haemorrhage	post procedural hematoma, procedural haemorrhage	incision site haemorrhage, anastomotic haemorrhage

Antibody induced thrombocytopenia, as can be caused by (low molecular weight) heparin, was observed in rare cases during the use of danaparoid sodium, but only in patients who were already sensitised to either heparin or low molecular weight heparin (see section 4.4).

All above terms in this section and synonym terms (with same or less severity) coded with the MedDRA dictionary are considered as 'listed'.

Haemorrhages are listed adverse events for danaparoid sodium. This also means that symptoms or signs which are clearly directly related to a haemorrhage (e.g. anaemia, decreased Hb, RBC, haematocrit, faintness, tiredness, tamponade) are listed adverse events.

Liver abnormalities such as changes in transaminase and alkaline phosphatase have been observed, but no clinical significance has been demonstrated.

Very rarely, cases of epidural and spinal haematomas were reported in association with prophylactic use of heparin or low molecular weight heparin in the context of peridural or spinal anaesthesia and of spinal puncture. These haematomas have caused various degrees of neurological impairment, including prolonged or permanent paralysis (see Section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:
Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In the event of serious bleeding other than caused by a surgical error, danaparoid sodium should be stopped and transfusion of fresh frozen plasma or, if uncontrollable, plasmapheresis should be considered. Although protamine partially neutralises the anticoagulant activity of danaparoid sodium the relevance for the reversal of the bleeding is not clear and therefore cannot be recommended. The effects of danaparoid sodium on anti-Xa activity cannot be antagonized with any known agent at this time.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antithrombotic agents - heparin group, ATC Code: B01AB06

Danaparoid sodium has been shown both in animal models and in human studies to be an effective antithrombotic substance. At therapeutic doses danaparoid sodium has no or only a minor effect on haemostatic plug formation, platelet function and platelet aggregability with no significant effect on bleeding time at the recommended doses. Occasionally, after high intravenous or subcutaneous doses, a prolonged bleeding time has been observed.

The anticoagulant activity of danaparoid sodium in clotting assays such as prothrombin time, activated partial thromboplastin time, kaolin cephalin clotting time and prothrombin time is small, and characterised by a very flat dose-response curve up to relatively high doses.

The ultimate step in blood coagulation, the fibrinogen-fibrin conversion, is critically dependent on prothrombin generation to which Factor Xa and thrombin contribute substantially. The anticoagulant profile of danaparoid sodium is characterised by a high ratio of anti-factor Xa/antithrombin activities, resulting in an effective inhibition of thrombin generation and thrombus formation. The anti-Xa activity is mediated by antithrombin-III and is not inactivated by endogenous heparin-neutralising factors. The small antithrombin activity is mediated by heparin co-factor II and antithrombin-III. The heparan sulphate fraction with low affinity for antithrombin-III, lacking significant effects on coagulation factors Xa and IIa *in vitro*, has been shown in animal studies to contribute substantially to the antithrombotic activity by an as yet unexplained mechanism.

Danaparoid sodium shows low cross-reactivity (<10%) with the heparin induced antibody. This can be explained by the absence of heparin in danaparoid sodium and its low degree of sulphation (see section 4.4).

Danaparoid sodium has also been shown to interfere with the interaction of the heparin-induced anti-platelet antibody and its target, thus potentially reducing platelet activation.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have primarily been based on the kinetics of relevant anticoagulant activities of danaparoid sodium, because no specific chemical assay methods are available.

In animal models the time courses of the thrombin generation inhibitory activity and antithrombotic activities of danaparoid sodium were strongly related, but the simplest to measure is the effect on plasma anti-Xa activity hence its use for monitoring purposes.

The absolute bioavailability of danaparoid sodium, as estimated from its effect on plasma anti-Xa activity, after subcutaneous administration approaches 100%. In humans the time to reach peak plasma anti-Xa activity levels is approximately 4-5 hours.

The half-lives of elimination of anti-Xa and thrombin generation inhibiting activities of approximately 25 hours (representing a sub-fraction of danaparoid that accounts for 50% of its antithrombotic activity) and 7 hours (representing the total antithrombotic activity of danaparoid), respectively, after both subcutaneous and intravenous administration are independent of the dose. Steady-state levels of plasma anti-Xa activity are usually reached within 4-5 days of dosing. Measured by thrombin generation inhibiting activity steady-state levels are reached earlier, i.e. within 1-2 days. Danaparoid sodium is mainly eliminated by renal excretion and animal experiments indicate that the liver is not involved in its metabolism.

Renal impairment
In patients with severely impaired renal function the half-life of elimination of plasma anti-factor Xa activity may be prolonged necessitating dose reduction (see Section 4.2).

5.3 Preclinical safety data

The results of pre-clinical studies do not add to the information included in the other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium sulphite
Sodium chloride
Hydrochloric acid
Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.
Do not freeze.
Keep the ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

1-ml glass ampoules containing 750 anti-factor Xa units (0.6ml) danaparoid sodium per ampoule (1250 anti-factor Xa units/ml) in packs of 10 or 20 ampoules.

6.6 Special precautions for disposal and other handling

Danaparoid sodium is compatible with, and therefore can be added to, infusions of saline (0.9%), dextrose (5%) and dextrose-saline.

It is advisable to discard the product when the visual appearance has changed or when the container is damaged.

7. MARKETING AUTHORISATION HOLDER

Viatris Products Limited,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

8. MARKETING AUTHORISATION NUMBER

PL 46302/0228

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 April 1993
Date of latest renewal: 09 October 1998

10. DATE OF REVISION OF THE TEXT

10/2025

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 °C.
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
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Station Close,
Potters Bar,
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United Kingdom.

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

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

This leaflet was last revised in 10/2025.

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

VIATRIS
3900497
11506841-02

VIATRIS

Description	Danaparoid Sodium, 750 IU/0.6 ml, 10	Date: 26-AUG-2025	Time: 14:00
Component Type	Leaflet (Insert)	Site Barcode/ DataMatrix	392
Affiliate Item Code	3900497	Viatris SAP No.	400557824
Superseded Affiliate Item Code	ART-5283-02	Vendor Job No.	NA
TrackWise Job No.	3900497	Artwork Proof No.	1
MA No.	PL 46302/0228	Client Market	United Kingdom
Supplier SAP No.	NA	Market Barcode Info	NA
New Supplier Code	11506841-02	3D Render ID	NA
Superseded Supplier Code	11506841-01	GTIN/PC	NA

No. of colours	1	Page Count	2 of 2
Colours	Black; Black 20%		
Non-Print Colours	Cutting Die		
Equate CMYK with			
Main Font	Univers LT Std	Body Text Size	8 pt
Dimensions	157 x 630 mm	Min Text Size used	8 pt