4.2 Posology and method of administration

In general monitoring of the dosage regimen is necessary to ensure that the therapeutic plasma anti-Xa level is maintained at a level of 0.5–0.8 units/ml during the first 48 hours, followed by 1 unit/ml during the subsequent 24 hours. If the dosage is inappropriate, this may result in osteoporosis or other bone problems.

5. Storage

Orgaran® is supplied in glass vacuum-sealed ampoules containing 0.6 ml. Each ampoule contains 1250 amidolytic units of danaparoid sodium, which is derived from animal chondroitin sulphate. One ml contains 0.65 mg danaparoid sodium and 0.32 mg sodium chloride, 0.02 mg sodium hydroxide and 0.04 mg potassium chloride.

6. More information about Orgaran

In this leaflet:

- In general Orgaran should be used with discretion, and a minor amount of care is needed if you are given doses of 250 or more amidolytic units/ml.
- In surgical patients it is advisable to give additional doses of Orgaran and to continue them until postoperative day 4.
- If you have an acute bacterial endocarditis, you should be given Orgaran immediately after treatment starts.
- If you have a heart valve disease, you should be given Orgaran immediately after treatment starts.
- If you have a history of asthma or bronchospasm, you should be given Orgaran immediately after treatment starts.
- If you have now or have had an allergy to any component of Orgaran, you should avoid giving Orgaran to patients who are allergic to the active substance or any of its components.
- If you have a history of asthma or bronchospasm, you should be given Orgaran immediately after treatment starts.
- If you are allergic to any component of Orgaran, you should avoid giving Orgaran to patients who are allergic to the active substance or any of its components.
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4.7 Effects on Ability to Drive

Other medicines may affect your ability to drive and use machines.

Orgaran is not known to have any effect on the ability to drive and therefore cannot be considered a relevant risk factor. However, it is recommended to consider the effects of the patient's medical condition.

4.8 Undesirable Effects

In clinical studies no adverse events have been reported in association with the use of Orgaran.

4.9 Overdosage

In overdose, the risks of the treatment are the same as with normal use. No specific antidote is available. The patient should be given adequate medical care according to the clinical situation. If necessary, haemodialysis may be considered. It is important to consider the possibility of reversal of the anticoagulant activity with protamine.

5. Pharmacological Properties

5.1 Prodrug

Orgaran contains a natural substance, danaparoid sodium, which is a prodrug of anticoagulant activity.

5.1.1 Mechanism of action

The anticoagulant activity of danaparoid sodium is mediated by heparin co-factor II and antithrombin-III and is not inactivated by endogenous heparin-neutralising factors.

5.1.2 Duration

Danaparoid sodium has no antiplatelet effects or haemostatic plug formation, is critically dependent on renal function, and has a half-life of 6 to 8 hours. Administration can be continued, if necessary, until the patient is hemodynamically stable. The anticoagulant activity ceases when there is a large drop in the number of blood platelets.

5.1.3 Indications

Orgaran is indicated for use in patients undergoing or following surgical procedures, undergoing anticoagulant therapy, and for prophylaxis of venous thromboembolism.

5.1.4 Contraindications

Orgaran should not be used if the patient has a history of danaparoid sodium or any of its excipients.

5.2 Pharmacodynamic Properties

5.2.1 Pharmacodynamics

Orgaran is usually given as a bolus dose, although it can also be used as a continuous intravenous infusion. The anticoagulant activity of danaparoid sodium is critically dependent on renal function, and has a half-life of 6 to 8 hours. Administration can be continued, if necessary, until the patient is hemodynamically stable. The anticoagulant activity ceases when there is a large drop in the number of blood platelets.

5.2.2 Plasma Levels

Orgaran is usually given as a bolus dose, although it can also be used as a continuous intravenous infusion. The anticoagulant activity of danaparoid sodium is critically dependent on renal function, and has a half-life of 6 to 8 hours. Administration can be continued, if necessary, until the patient is hemodynamically stable. The anticoagulant activity ceases when there is a large drop in the number of blood platelets.

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Danaparoid sodium has no antiplatelet effects or haemostatic plug formation, is critically dependent on renal function, and has a half-life of 6 to 8 hours. Administration can be continued, if necessary, until the patient is hemodynamically stable. The anticoagulant activity ceases when there is a large drop in the number of blood platelets.

5.3 Practical Use

5.3.1 Administration and Dosage

Orgaran should be given as a bolus dose, although it can also be used as a continuous intravenous infusion. The anticoagulant activity of danaparoid sodium is critically dependent on renal function, and has a half-life of 6 to 8 hours. Administration can be continued, if necessary, until the patient is hemodynamically stable. The anticoagulant activity ceases when there is a large drop in the number of blood platelets.