

Orgaran

danaparoid sodium

Consumer Medicine Information

Before administration of this medicine please read this leaflet carefully.

If you have any questions or worries, ask your doctor or pharmacist.

What is in this leaflet

This leaflet is designed to provide you with information on Orgaran.

It does not contain all the available information.

It does not take the place of talking to your doctor.

Please read it carefully. If you still have any questions or concerns regarding Orgaran and its use, please ask your doctor.

Always carry a medical information card stating which medicines you are taking. This may be very important should you become involved in an accident.

What Orgaran is used for

Orgaran is used to help prevent blood clots forming in your veins. Blood clots which form in veins may restrict the blood flow resulting in tissue death through lack of blood. Furthermore, parts of the clot are liable to break off and may block the blood circulation in the lungs. This may have fatal consequences.

If you are bedridden, you have an increased risk of clot formation in the veins of the legs, especially if you have undergone an operation. You may receive Orgaran to help prevent the formation of blood clots.

Before you are given it

Your doctor will assess your need before using Orgaran.

When Orgaran should not be administered:

- If you suffer from a birth condition which causes you to bleed severely e.g. haemophilia
- If you have a known sensitivity to Orgaran or any of the ingredients of the product e.g. sodium sulfite.
- If you have a severe kidney and/or liver disorder.
- If you have severe high blood pressure.
- If you have a severe gastric or duodenal ulcer unless it is the reason for your operation.
- If you test positive to an in vitro aggregation test in the presence of Orgaran.
- If your retina is affected by diabetes.
- If you have acute infection of the inner lining and valves of the heart (acute bacterial endocarditis).
- If you are in the acute stage of a stroke caused by bleeding.
- If you are bleeding uncontrollably.

Extra medical supervision by your doctor may be necessary in certain circumstances.

Before you are administered this medicine, you must inform your doctor if you have or ever have had any of the following conditions:

- Kidney or liver damage with impaired blood circulation.
- Ulcers of the stomach or intestine
- Other conditions or diseases which may lead to an increased risk of bleeding into a vital organ or site.
- A sensitivity to sulfite, which, especially in asthma patients can result in severe allergic reactions.
- Any other undesirable effects that you think may be due to this medication.

If you are pregnant, or may suspect that you are or if you want to start breast feeding then you must consult your doctor.

How Orgaran is given

How much

The normal dose administered is 750 anti-Xa units (0.6 mL ampoule), twice a day, for up to 10 post-operative days.

How it is injected

Orgaran is administered by subcutaneous (under the skin) injection by a doctor or nurse.

Overdosage

An overdose of Orgaran may result in an unusual loss of blood which in the first instance is corrected by stopping further administration of Orgaran. In some cases, a blood transfusion will be necessary.

While you are using Orgaran

Other medicines may influence the effect of Orgaran or vice-versa. Inform your doctor if you are taking (or intend to take) other medicines such as:

- Medicines which interfere with platelet function such as aspirin and non-steroidal anti-inflammatory drugs (e.g. these include common painkillers such as ibuprofen and naproxen).
- Medicines which may cause peptic ulcers such as corticosteroids.

The combination of Orgaran with aspirin may cause an extension to bleeding time.

Side effects

Orgaran may have unwanted side effects in a few people. All medicines have side effects. Sometimes they are serious but usually they are not. Do not be alarmed by the list below. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- bruising and/or pain at the site of injection
- skin rashes
- other localised or general sensitivity

If you are on Orgaran and are given an epidural anaesthetic (a medicine injected in the spine during surgery to reduce pain) there is an increased risk of developing a spinal bruise which could possibly result in long term or even permanent paralysis. Your doctor can advise you further on this.

Other side effects not listed above may also occur in some people.

After using it

Storage

It is unlikely that you will have to store Orgaran as it is not self administered. Orgaran is a prescription only product with a shelf-life of 3 years when stored below 30°C. Orgaran must not be administered beyond the expiry date shown on the ampoule and carton.

Disposal

If you have any unused medicine, return it to your pharmacist. This is unlikely for Orgaran, as the doctor will normally not give the product to you to keep.

Product Description

Orgaran is a clear, colourless to slightly yellow liquid in a 0.6 mL ampoule. Packs of ten 0.6 mL ampoules.

Active ingredient:

- danaparoid sodium

Other ingredients:

- sodium sulfite
- sodium chloride
- hydrochloric acid (to adjust pH)
- water for injections.

Distributed by:

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This leaflet was revised in July 2024.

Australian registration number:

AUST R 46096