

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Orgaran 750 anti-factor Xa units solution for injection, Danaparoid sodium

#### **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 your 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 Orgaran is and what it is used for
2. Before you use Orgaran
3. How to use Orgaran
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#### **1. What Orgaran is and what it is used for**

Orgaran solution for injection contains danaparoid sodium and is one of a group of medicines that are called antithrombotics.

Orgaran is used to prevent blood clots from forming in the blood-vessels and is used in patients who have an increased chance of getting a blood clot (for example in patients who are bedridden and have had surgery).

Orgaran can also be used to prevent or treat blood clots in patients who can no longer be given heparin because they have a condition called heparin induced *thrombocytopenia* (a large drop in the number of platelets due to hypersensitivity to heparin).

#### **2. Before you use Orgaran**

##### **Do not use Orgaran**

- if you are **allergic** (hypersensitive) to danaparoid sodium or any of the other ingredients of Orgaran
- if you had a hemorrhagic **stroke** (due to a bleed in the brain) in the last three months
- if you have a **bleed** and it cannot be stopped
- if you have severely **high blood pressure** that can't be helped
- if you **have damage to the eye** caused by diabetes
- if you have an **infection of the heart valves** (*acute bacterial endocarditis*)
- if you are being given **heparin** (a frequently used antithrombotic) to treat blood clots you should not have a **spinal or epidural** anaesthetic for surgery.

**tell your doctor if any of these applies to you**

##### **Take special care with Orgaran**

- if you have or ever have had any of the following conditions:
  - **former treatment** with heparins (a group of frequently used antithrombotics) resulting in a large drop in the number of blood platelets (*thrombocytopenia*) and a blood test showing that Orgaran may cause a similar effect
  - **tendency to bleed** severely, for example haemophilia, or an increased bleeding risk

- **hepatic or renal** disorders
  - **ulcer(s)** in the stomach or small intestine
  - hypersensitivity to **sulphite**, as this can cause severe allergic reactions in asthma patients
  - if Orgaran is used during **heart bypass operation**.
  - in the case of medical examination or surgery for which a **spinal/epidural injection** is necessary.  
Extra supervision may be needed.
- **tell your doctor if any of these applies to you**

### **Using other medicines**

→ **tell your doctor if you are taking or have recently taken any other medicines**, including medicines obtained without a prescription. Orgaran may affect other medicines or be affected by them.

Medicines which may increase the risk of bleedings when taken at the same time as Orgaran:

- medicines used to **dissolve blood clots**
- **aspirin** and other **anti-inflammatory drugs** (like *NSAIDs*), for example for treatment of rheuma
- medicines that may cause **ulcers** (such as *corticosteroids*).

### **Using Orgaran with food and drinks**

Food and drinks are not known to have effects on the effectiveness of Orgaran.

### **Pregnancy and breast-feeding**

→ **tell your doctor if you are pregnant or might be pregnant, or if you are breast-feeding**. Your doctor may still give you Orgaran if alternative medication is not available for you.

### **Driving and using machines**

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

### **Important information about some of the ingredients of Orgaran**

Orgaran contains **sodium sulfite E221**. Tell your doctor if you have ever had hypersensitivity to sulfite, as this can cause severe allergic reactions in asthma patients.

## **3. How to use Orgaran**

Orgaran is injected by a doctor or nurse.

### **The dose**

The dose for the prevention of blot clots is 1 ampoule (750 units), twice-a-day, for up to 14 days. Sometimes you may be given Orgaran for longer than this.

Patients with a large drop in the number of blood platelets during heparin administration (*thrombocytopenia*, see Section 1) usually need higher doses.

Your doctor will work out the dose of Orgaran you need based on:

- the underlying disease you are suffering from
- the risk of blood clots
- the risk of bleeding
- your state of health and your physical characteristics (such as weight)
- whether or not you are hypersensitive to heparins

Orgaran may be given to children. Your doctor will take into account age and weight to determine to dose.

### **How Orgaran is given**

Orgaran will be given to you by a doctor or nurse. Orgaran is given either as an injection under the skin or as an injection into a vein.

### **If you use more Orgaran than you should**

As your doctor or nurse will be monitoring your condition carefully it is unlikely that you will be given too much Orgaran and, when needed, they will adjust doses.

If too high a dose is given you may notice unusual bleeding. This may show by:

- nosebleeds, bleeding gums
- blackened stools (may indicate blood loss from stomach or intestines)
- blood in the urine
- unusually heavy periods

→**Tell your doctor or nurse if you notice any of these or other symptoms of unusual blood loss**

### **If you forget to use Orgaran**

As your doctor and nurse carefully check your medical condition, it is unlikely that you will receive too low a dose Orgaran. If needed, they will adjust the dose.

### **If you stop using Orgaran**

Your doctor will decide when to stop Orgaran use.

If you have any further questions on the use of this product, ask your doctor.

## **4. Possible side effects**

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

Orgaran may increase the risk of bleeding.

Some side effects are more common than others:

### **Common side effects**

(less than 1 in 10, but more than 10 out of 100 patients given Orgaran)

- a large drop in the number of blood platelets (*thrombocytopenia*) in patients already hypersensitive to heparin
- skin rash
- enhanced bleeding after your operation

### **Uncommon side effects**

(less than 1 in 100, but more than 1 out of 1000 patients given Orgaran)

- bruises or pain near the injection site
- allergic (hypersensitivity) reactions

### **Rare side effects**

(less than 1 in 1000 patients given Orgaran)

- enhanced bleeding or leaking near the operation site
- a drop in the number of blood platelets due to an auto-immune disorder (*auto-immune thrombocytopenia*)

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

When heparin (an antithrombotic) is used at the same time as a spinal injection, bruising of the spine may occur. This occurs very rarely and not necessarily with Orgaran (see section 2).

However, if you notice any of the following symptoms:

- back pain
- tingling, numbness or weakness in the legs

- bowel or bladder problems
- tell your doctor or nurse immediately** as you may require treatment

## 5. How to store Orgaran

The hospital will keep Orgaran according to the correct storage conditions.

Keep out of the reach and sight of children.

Do not store above 30 °C. Do not freeze.

Do not use if the solution contains particles.

Store in the original package in order to protect from light.

Do not use Orgaran after the expiry date which is stated on the carton after “exp”. The expiry date refers to the last date of that month.

## 6. Further information

### What Orgaran contains

- The active substance is danaparoid sodium (750 anti-factor Xa units in 0.6 mL solution).
- The other ingredients are sodium sulphite E221, sodium chloride, water for injection, and hydrochloric acid (to adjust pH).

### What Orgaran looks like and contents of the pack

Orgaran is a clear, colourless to pale yellow solution for injection.

It is available in glass ampoules (either 10 or 20 per box). Each ampoule contains 0.6 mL solution with 750 anti-factor Xa units danaparoid sodium.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### *Marketing Authorisation Holder:*

Mylan IRE Healthcare Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Ireland

#### *Manufacturer:*

NV Organon, Kloosterstraat 6, 5349 AB Oss, The Netherlands.

**This leaflet was last approved in April 2014**