

Package leaflet: Information for the user

Warfarin Orion 2.5 mg tablets

warfarin sodium

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Warfarin Orion is and what it is used for
2. What you need to know before you take Warfarin Orion
3. How to take Warfarin Orion
4. Possible side effects
5. How to store Warfarin Orion
6. Contents of the pack and other information

1. What Warfarin Orion is and what it is used for

Warfarin Orion is used to prevent thromboembolism (blood clots) or to treat thromboembolism or its complications. Warfarin Orion reduces the tendency of blood to form clots.

This medicine is used to:

- prevent and treat deep venous thrombosis of the lower limbs (blood clots in the veins of lower limbs) and pulmonary embolism (blood clots in the pulmonary arteries)
- prevent formation of blood clots in some patients with atrial fibrillation (a cardiac arrhythmia)
- prevent formation of blood clots after large myocardial infarction
- prevent formation of blood clots in some patients with prosthetic heart valves (after cardiac valve replacement).

2. What you need to know before you take Warfarin Orion

Do not take Warfarin Orion

- if you are allergic to warfarin sodium or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant during first trimester or last four weeks (see also section Pregnancy and breast-feeding)
- if you have a bleeding tendency (haemophilia, von Willebrand disease, deficiency of blood platelets (thrombocytopenia) or platelet function disorders)
- if you have severe hepatic insufficiency or hepatic cirrhosis
- if you have untreated or uncontrolled hypertension
- if you have had recent intracranial bleeding
- if you have tendency to fall due to neurological or other health-related conditions
- if you have had the surgery of the central nervous system or the eye recently or if you may undergo such surgery in the near future
- if you have earlier suffered from gastrointestinal tract hemorrhages (e.g. perforated ulceration, bloody or black stools, vomiting of blood) or from urinary track bleeding (unexplained blood in urine)

- if you suffer from endocarditis or pericarditis, or if you have a pericardial effusion
- if you have dementia, psychoses, alcoholism, or another situation where the anticoagulant treatment cannot be administered safely
- if you use St. John's wort (*Hypericum perforatum*)
- if you are taking other medicines to prevent blood clotting (e.g. dabigatran, apixaban, rivaroxaban, edoxaban) except when changing anticoagulant treatment.

Warnings and precautions

Talk to your doctor or pharmacist before taking Warfarin Orion

- if you use, start or stop to use other medicines during treatment with Warfarin Orion (see section Other medicines and Warfarin Orion)
- if you have hyper- or hypothyreosis
- if you have cardiac insufficiency associated with sudden exacerbations (episodes increased oedema and shortness of breath)
- if you have other form of hepatic insufficiency than those mentioned above, or hepatitis
- if you have renal insufficiency
- if you are having dental or any other surgery in the near future, consult your doctor.

Drastic changes in dietary habits should be avoided as the amount of vitamin K in food may affect therapy with warfarin. Conditions which may affect therapy are transition to a vegetarian diet, extreme dieting, depression, vomiting or diarrhea.

Other medicines and Warfarin Orion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines

Very **many** medicines affect the potency of Warfarin Orion either by enhancing or reducing it. Glucosamine (for osteoarthritis) may increase the effect of Warfarin Orion.

New medicines must not be initiated and old medicines discontinued without first consulting a doctor. All changes in the concomitant medicines may alter the balance of the oral anticoagulation and more frequent blood tests may be needed.

If you need analgesics, contact a doctor. Most analgesics available without prescription must not be used concomitantly with Warfarin Orion. However, for temporary relief of pain or fever, preparations containing only paracetamol as the active ingredient can be used.

Herbal medicines and natural products

If you are already using some of the following herbal medicines, you must consult with a doctor before ending the use of the herbal medicine. Ginkgo (*Ginkgo biloba*), garlic (*Allium sativum*), dong quai preparation (*Angelica sinensis*), papaya (*Carica papaya*), and danshen (*Salvia miltiorrhiza*) may potentiate the effect of Warfarin Orion. St John's wort (*Hypericum perforatum*) and ginseng (*Panax spp.*) on their part may reduce the effect. Therefore, the use of these herbal medicines must not be started or ended during Warfarin Orion treatment without consulting a doctor.

Warfarin Orion with food, drink and alcohol

Ingestion of vitamin K reduces the effects of Warfarin Orion. Therefore, ingestion of vitamin K containing foodstuffs during warfarin treatment should be as steady as possible. Sudden changes in the diet should be avoided. The most abundant vitamin K sources are green vegetables, leaves and herbs.

Some of these are listed below. It is not necessary to avoid their use, but the daily amounts should be as steady as possible: amaranth leaf, avocado, broccoli, Brussels sprout, cabbage, canola oil, chayote leaf, chives, coriander, cucumber skin (but not cucumber without skin), endives, kale leaf, kiwifruit, lettuce leaf, mint leaf, mustard greens, olive oil, parsley, peas, pistachio nuts, purple seaweed laver, spinach leaf, spring onion, soybeans, soybean oil, tea leaves (but not tea), turnip greens, or watercress.

Cranberry juice and other cranberry products may potentiate the effect of warfarin and therefore concomitant use should be avoided.

Do not drink large amounts of alcohol while you are taking warfarin. Heavy alcohol intake and concomitant liver failure may potentiate the effect of warfarin.

Warfarin Orion and smoking

Smoking may affect the efficacy of warfarin. You might need to have more frequent laboratory investigations in case you have smoked for a long time and you stop smoking while on warfarin therapy. Please contact your doctor if this applies to you.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Warfarin Orion should not be used during the first trimester or last four weeks of pregnancy. If possible, Warfarin Orion should be avoided during the whole period of pregnancy, but in special circumstances treatment may be considered by specialist clinician.

Warfarin is not excreted in the breast milk, so breast feeding can be continued during Warfarin Orion treatment.

Driving and using machines

Warfarin Orion has no influence on driving or using machines.

Warfarin Orion contains lactose

The tablets contain lactose (51.4 mg/tablet). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Other excipients

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

3. How to take Warfarin Orion

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

It is necessary to have laboratory investigations at regular intervals. The dosage is individually adjusted for you and the doses may differ from day to day. It is absolutely necessary to follow the dosing instructions and attend the laboratory controls.

If you take more Warfarin Orion than you should

If you take or if someone else has taken an excessive dose of Warfarin Orion, a doctor must be contacted for further instructions. Do not provoke vomiting. If a large overdose has been taken, activated charcoal can be administered for the first aid, but despite that the person must contact a doctor immediately as further treatment might be needed.

If you forget to take Warfarin Orion

If you forget one dose and you notice it within 12 hours, you can take the forgotten dose immediately. Take the next dose normally. If it has been more than 12 hours since you forgot the dose, divide the forgotten dose into two or three parts and take them together with the next doses so that the weekly

dose does not change. If you forget more than one dose, you must contact a doctor for further dosing instructions.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Warfarin Orion

If therapy with Warfarin Orion is discontinued, the anticoagulant effects may persist for 2-5 days.

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.

Contact a doctor immediately if you experience any of the following during the treatment with Warfarin Orion:

- Increased tendency or sensitivity for bruising, nasal or gingival bleeding, blood in the urine, black or bloody stools, vomiting of blood or increased or prolonged menstrual bleeding. These symptoms may be signs of excessive warfarin effect.
- A painful skin rash. On rare occasions warfarin can cause serious skin conditions, including one called calciphylaxis that can start with a painful skin rash but can lead to other serious complications. This adverse reaction occurs more frequently in patients with chronic kidney disease.

Other side effects that may occur:

Common (may affect up to 1 in 10 people):
Bleeding, nausea, vomiting, diarrhoea.

Rare (may affect up to 1 in 1,000 people):
Coumarin-induced death of skin tissues, purple toe syndrome (purplish and painful skin lesions in the toes or soles).

Very rare (may affect up to 1 in 10,000 people):
Hypersensitivity reactions manifested usually as skin rash, reversible elevation of hepatic enzyme values, biliary pain, inflammation of veins, reversible hair loss, prolonged painful erection (usually in the beginning of treatment), calcification of the windpipe, cholesterol embolism.

Not known (frequency cannot be estimated from the available data):
Accumulation of calcium in the wall of blood vessels leading to progressive and painful skin ulcers. Impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Warfarin Orion

This medicinal product does not need any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Warfarin Orion contains

- The active substance is 2.5 mg of warfarin sodium/tablet.
- The other ingredients are lactose, maize starch, calcium phosphate, povidone, magnesium stearate.

What Warfarin Orion looks like and contents of the pack

White to off-white, round biconvex uncoated tablet (7 mm in diameter). Cross-line on both sides. The tablet can be divided into two equal doses.

Pack size:
100 tablets.

Marketing Authorisation Holder

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer

Orion Corporation Orion Pharma
Orionintie 1
FI-02200 Espoo
Finland

Orion Corporation Orion Pharma
Joensuunkatu 7
FI-24100 Salo
Finland

This medicine is authorized in the Member States of the European Economic Area under the following names:

Denmark: Warfarin Orion
Norway: Warfarin Orion 2.5 mg tablets
Sweden: Warfarin Orion 2.5 mg tablets
Finland: Warfarin Orion 2,5 mg tablets

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