

ORFARIN TABLET

Warfarin Sodium (3mg and 5mg)

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What Orfarin is used for

Orfarin tablets are used to prevent thromboembolism (blood clots) or to treat thromboembolism or its complications. Orfarin tablets reduce the tendency of blood to form clots.

Your doctor will explain to you, what disease is treated or prevented by this medicine. Most commonly, this medicine is used to:

- prevent and treat deep venous thrombosis of the lower limbs (blood clots in the blood vessels of lower limbs) and pulmonary embolism (blood clots in the blood vessels of the lung)
- prevent formation of blood clots during rapid and irregular heart beating
- prevent formation or reoccurrence of blood clots after heart attack
- prevent formation of blood clots after heart valve replacement.

How Orfarin works

Orfarin belongs to a group of medicine called anticoagulants.

These medicines increase the time it takes for your blood to clot.

Before you use Orfarin

- When you must not use it

Do not use Orfarin if you:

- are in the first trimester and last four weeks of pregnancy.
- suffer from a bleeding tendency (haemophilia, von Willebrand disease, deficiency of blood platelets (thrombocytopenia) or platelet function deficit)
- suffer from severe liver insufficiency or liver cirrhosis
- suffer from untreated high blood pressure
- have had recent intracranial bleeding
- have tendency to frequent falls due to neurological or other health-related conditions
- have had the surgery of the central nervous system or the eye recently or if you may undergo such surgery in the near future
- suffer from endocarditis (inflammation of the inner layer of the heart, the endocardium) or pericarditis (inflammation of the pericardium [the fibrous sac surrounding the heart]), or if you have a pericardial effusion (an abnormal accumulation of fluid in the pericardial cavity)
- have conditions predisposing to the gastrointestinal or urinary tract bleeding, e.g. previous gastrointestinal bleeding complications, diverticulitis, or malignancies.
- are allergic (hypersensitive) to warfarin sodium or any of the other ingredients of Orfarin.
- use St. John's wort (*Hypericum perforatum*).

- have dementia, psychoses, alcoholism, or another situation where the anticoagulant treatment cannot be administered safely
- do not take Orfarin together with miconazole oral gel

- Before you start use it

Please tell your doctor if you:

- are pregnant or plan for a pregnancy
- suffer from thyroid problem
- suffer from heart and breathing problem with symptom of increased oedema and shortness of breath
- suffer from other form of liver insufficiency than those mentioned above, or hepatitis
- suffer from kidney insufficiency
- are having dental or any other surgery in the near future
- use, start or stop to use other medicines during treatment with Orfarin (see section *Taking other medicines*).

Some commonly used medicines and products that may interfere with Orfarin include:

- Miconazole

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, herbal medicines or natural products.

Medicines

Many medicines affect the potency of Orfarin tablets either by enhancing or reducing it. New medicines must not be initiated and old medicines discontinued

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without first consulting a doctor. All changes in the concomitant medicines may alter the balance of the oral anticoagulation and more frequent INR determinations (laboratory investigations) may be needed.

If you need pain killer, contact a doctor. Most pain killer available without prescription must not be used concomitantly with Orfarin. 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 Orfarin. 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 Orfarin treatment without consulting a doctor.

Using Orfarin with food and drink

Ingestion of vitamin K effects the Orfarin treatment. 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.

How to use Orfarin

- How much to use

You receive detailed instructions about your Orfarin treatment from your doctor, hospital, or the health center. Take Orfarin tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

It is necessary to have blood test at regular intervals. The dosage is individually adjusted for you and the doses may differ from day to day. Dosing instructions are written on your oral anticoagulation follow up card. From this card you should find out the purpose of your oral anticoagulant treatment, the target anticoagulant effect (e.g. INR 2.0 to 3.0, or INR 2.5 to 3.5), and the time of the next blood test. It is absolutely necessary to follow the dosing instructions and attend the blood test.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Orfarin for as long as your doctor recommends.

If therapy with Orfarin is discontinued, the anticoagulant effects may persist for 2–5 days.

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

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. It is recommended to write down the taken doses on your follow up card.

- If you use too much (overdose)

If you take or if someone else has taken an excessive dose of Orfarin, a doctor must be contacted for further instructions. Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

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

- Things you must do

Take your medicine exactly as your doctor has told you.

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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, diarrhea, steatorrhea (the presence of excess fat in feces) or malabsorption of other causes

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Orfarin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Important information about some of the ingredients of Orfarin

The tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

Side effects

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

Common side effects (occurs in more than 1 of 100 patients):

- Mild bleeding (nasal or gingival bleeding, or bruising)
- Blood in the urine
- Black or bloody stools
- Increased or prolonged menstrual bleeding, or other bleeding
- Nausea
- Vomiting

- Diarrhoea.

Rare side effects:

Coumarin necrosis (skin and soft-tissue complication of oral anticoagulation therapy), purple toe syndrome (purplish and painful skin lesions in the toes or soles).

Very rare side effects:

- Hypersensitivity reactions manifested usually as skin rash
- reversible elevation of liver enzyme values
- biliary (gallbladder, bile ducts, or bile) pain
- development of vasculitis (inflammation of your blood vessels)
- reversible hair loss
- priapism (prolonged erection of the penis) usually in the beginning of treatment
- tracheal calcification (radiological finding of the middle aged and elderly and is usually of no clinical significance)
- cholesterol embolism (an embolism of lipid debris that may cause mechanical plugging at small blood vessels and end organ damage)

Frequency 'not known':

Impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy).

Tell your doctor straight away if you have any of the following side effects:

- 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.

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.

Important!

Contact doctor immediately if you experience any of the following during the treatment with Orfarin

- 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.
- Allergic reaction – the signs may include swelling of your face, lips, tongue or throat, difficulty in breathing or swallowing, severe itching of your skin with raised lumps.
- Red or purple swollen or painful patches on your skin that look like bruises or blood filled blisters that turn black
- Painful toes which become purple or dark in color.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.moh.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

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Storage and Disposal of Orfarin

- Storage

Orfarin 3 mg Tablet: Store below 30 °C.

Orfarin 5 mg Tablet: Store below 25 °C.

Store in the original package with a desiccant capsule. Keep the jar tightly closed and in the outer carton in order to protect from light and moisture.

Keep out of the reach and sight of children.

Do not use Orfarin after the expiry date which is stated on the package.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Orfarin 3 mg Tablet: Light blue or light blue may be spotted, flat bevelled edged and scored uncoated tablets with a diameter of 7 mm and code ORN 17.

Orfarin 5 mg Tablet: Pink or pink may be spotted, flat bevelled edged and scored uncoated tablets with a diameter of 7 mm and code ORN 18.

The tablets can be divided into equal halves.

- Ingredients

- Active ingredient

The active substance is 3 mg or 5 mg of warfarin sodium/tablet.

- Inactive ingredients

The other ingredients are lactose monohydrate, maize starch, gelatin, magnesium stearate and colourants: indigo carmine (E 132) in the 3 mg tablets (light blue), and erythrocine (E 127) in the 5 mg tablets (pink).

- MAL number(s):

Orfarin 3mg Tablet: MAL19921323AZ

Orfarin 5mg Tablet: MAL20041004AZ

Manufacturer

Orion Corporation, Orion
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FI-02200 Espoo Finland

Product Registration Holder

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