

PACKAGE LEAFLET: INFORMATION FOR THE USER

FARIN

5 mg tablets

WARFARIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What FARIN is and what it is used for
2. Before you take FARIN
3. How to take FARIN
4. Possible side effects
5. How to store FARIN
6. Further information

1. WHAT FARIN IS AND WHAT IT IS USED FOR

Farin contains the active substance warfarin, which belongs to the group of medicines called anticoagulants. It works by reducing the coagulation or preventing clotting and the formation of blood clots in blood vessels.

Farin is used for preventing the formation and treating thromboembolism (blood clots) in the following conditions:

- Deep vein thrombosis and pulmonary embolism,
- Atrial fibrillation, artificial heart valves and rheumatic heart disease.

Farin is given in some cases after a myocardial infarction and stroke (TIA transient ischemic attack) for the prevention of thromboembolic complications.

2. BEFORE YOU TAKE FARIN

Warn your doctor if you are taking other medicines, have a chronic disease, a metabolic disorder, you are hypersensitive to medicines or you have had an allergic reaction to some of them.

Do not take FARIN in case of

Hypersensitivity to warfarin or other ingredients of the medicine,

- Pregnancy (first and third trimester)
- 48 hours after birth,
- Significant hemorrhage and increased susceptibility to bleeding - gastric or duodenal ulcers, hemorrhagic blood disorders, cerebrovascular disorders (stroke), aneurysm in the CNS, aortic dissection, bacterial endocarditis,
- Recent or planned surgical procedures with the risk of serious bleeding (surgically induced brain, eye or spine)
- Serious damage to the kidneys and liver,
- Severe and uncontrolled hypertension,
- Co-administration with medicines that increase the risk of bleeding (fibrinolytic).

In case of intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

Take special care with FARIN in

Prior to application of the medicine inform your doctor if you have a disease of the heart, liver, kidney, thyroid gland, stomach ulcers or duodenum, hypertension, bacterial endocarditis, or any disorder of blood (hemophilia, thrombophilia, anemia, etc.).

It is necessary to inform your doctor if you have had a stroke or a surgical intervention, including tooth extraction.

The risk of bleeding will also be increased if you are taking other medications (eg, non-steroidal anti-inflammatory medicines - NSAIDs) or herbal products (eg, St. John's wort, cranberry), then if you have more than 65 years, or in the case of malignancy or trauma.

Also, tell your doctor if you have recently lost/gained a significant body weight, stopped smoking, then if you are suffering from some acute illness, had vomiting or diarrhea, took a greater amount of alcohol, or some kind of food rich in vitamin K (green leafy vegetables, broccoli, liver).

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. Medicines that should not be used concomitantly with warfarin are fibrinolytic - medicines that dissolve blood clots (streptokinase, alteplase).

At the same time the use of other medicines may increase or decrease the effect of warfarin, so have to be administered with caution, and should be avoided.

Medicines the application of which should be avoided or used with caution and increased supervision: medicines that reduce blood clotting (unfractionated heparin - low molecular weight heparin; direct thrombin inhibitors - bivalirudin, dabigatran; synthetic factor Xa inhibitors - fondaparinux, rivaroxaban), medicines that can inhibit platelet activity or process of hemostasis (clopidogrel, dipyridamole; antagonists of glycoprotein IIb / IIIa receptor - eptifibatide, tirofiban, abciximab; prostacyclin), sulfapyrazone, antidepressants (tricyclics and SSRIs), NSAIDs (including aspirin and a selective COX-2 inhibitors - coxibs).

Medicines that increase the activity of warfarin are: allopurinol, antiarrhythmic medicines (amiodarone, propafenone), acetaminophen (prolonged regular use), certain antibiotics (erythromycin, azithromycin, sulfamethoxazole, metronidazole), antifungals from the group azoles (ketoconazole, fluconazole), chemotherapy medicines (capecitabine , erlotinib), disulfiram, omeprazole, tamoxifen, methylphenidate, lipid lowering medicines (fibrates, fluvastatin), zafirlukast.

Medicines which reduce the effect of warfarin are: azathioprine, anticonvulsants (barbiturates, phenytoin, carbamazepine), griseofulvin, oral contraceptives containing estrogen, primidone, rifampicin. Vitamin K reduces the anticoagulant effect of warfarin. Orlistat can reduce the absorption of vitamin K, while cholestyramine and sucralfate may reduce the absorption of warfarin.

Corticosteroids, nevirapine, ritonavir may adversely affect the effect of warfarin (increase or decrease the effect).

Herbal products: St. John's wort should not be used together with warfarin, because it is proven to reduce the concentration of warfarin in plasma, and therefore its effectiveness. It is not advisable to use cranberries during treatment with warfarin due to increased risk of bleeding. If you use preparations or cranberry juice in the treatment of urinary tract infections, be sure to tell your doctor about it.

Acute administration of large amounts of alcohol can increase the effect of warfarin, while in the case of chronic alcoholism effect of warfarin is decreased.

Taking food and drink with FARIN tablets

While taking Farin it is not recommended to use alcohol because it can affect the action of warfarin.

Anticoagulant activity of warfarin can be reduced by foods rich in vitamin K (liver, broccoli, green leafy vegetables). It is not advisable to use cranberry and grapefruit during treatment with warfarin. Patients should seek medical advice before the changes in the diet.

Pregnancy and breast-feeding

Warfarin should not be used during pregnancy (first and third trimester) because of the possible harmful effects on the fetus. Women of childbearing age, who are receiving warfarin, should use effective contraception during treatment.

Farin can be used during breastfeeding. Warfarin passes into breast milk in very small amounts and has no anticoagulant effect on the infant.

Driving and using machines

FARIN should not affect your ability to drive and use machines.

Other warnings

In case of intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

3. HOW TO TAKE FARIN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The medicine is taken orally.

The dosage is individual. Your doctor will determine the appropriate dosage depending on the disease. Dose will be adjusted in accordance with the results of laboratory blood tests, which will be conducted regularly during treatment.

The usual initial dose is 10 mg of warfarin for two days. In most cases starting dose of 5 mg per day is sufficient. In elderly patients and in those with an increased risk of bleeding, starting dose may be less than 5 mg per day.

Maintenance doses are from 3 to 9 mg daily. The medicine is taken daily at the same time.

If you take more FARIN than you should

Contact your doctor. If possible, bring a tablet, this instruction or packaging with you to show the doctor what you have taken.

Overdose may be manifested by bleeding from a variety of tissues and organs (blood in the urine-hematuria, black stool-melena, excessive menstrual bleeding, bleeding in the skin-petechiae, ecchymosis, bleeding from the gums or other mucous membranes, bleeding from shaving cuts, injuries, etc.).

If you forget to take Farin chewable tablets

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

If you forget to take your medicine, take the missed dose if you remember in the next 2-3 hours.

If it has been more time, take the missed dose the next day at the appointed time, and be sure to tell your doctor about it.

If you stop taking FARIN

You should not suddenly stop taking the medicine without consulting your doctor.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

Immediately contact your doctor if in the course of administration occur fever, shortness of breath or suffocation.

During the application of FARIN may occur bleeding in the gastrointestinal tract, urogenital tract, central nervous system, rectal bleeding or bleeding from the nose. Also may occur: fever, nausea, vomiting, diarrhea, black stools-melena, hypersensitivity reactions, skin reactions (itching, rash, purpura, skin necrosis syndrome violaceous finger), alopecia (hair loss), jaundice, hepatic dysfunction and inflammation of the pancreas (pancreatitis). There might be changes in laboratory tests of blood (a drop in hemoglobin and hematocrit).

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE FARIN

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use FARIN after the expiry date which is stated on the label.

Expiration date: 5 years.

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

6. FURTHER INFORMATION

What FARIN contains

The content of active substance:

1 tablet contains 5 mg of warfarin sodium.

Other ingredients: lactose monohydrate; starch, corn; Cellulose, microcrystalline povidone; magnesium stearate.

What FARIN looks like and contents of the pack

Round biconvex tablets, white to almost white, with indicated division line on one side.

Packing:

3 AL / PVC hard PVC blisters with 10 tablets (30 tablets) in a box.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

Galenika ad . Batajnički drum bb, 11080 Belgrade, Serbia