

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Coumadin 1 mg tablets

Active ingredient and its quantity:

Each tablet contains:

warfarin sodium 1 mg

Coumadin 2 mg tablets

Active ingredient and its quantity:

Each tablet contains:

warfarin sodium 2 mg

Coumadin 2.5 mg tablets

Active ingredient and its quantity:

Each tablet contains:

warfarin sodium 2.5 mg

Coumadin 5 mg tablets

Active ingredient and its quantity:

Each tablet contains:

warfarin sodium 5 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients' and section 6, 'Additional information'.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

- It is important to take the correct dosage. If you have difficulties, ask for help. If you take the wrong dose or a dose that is too high, consult your doctor.
- Always tell your doctor, surgeon, nurse, dentist or pharmacist that you are taking this medicine.
- Do not take new medicines without checking that it is safe to take them with Coumadin, especially aspirin, ibuprofen and other non-steroidal anti-inflammatory drugs (NSAIDs), because these medicines may increase the risk of bleeding.
- Certain illnesses and foods may affect the treatment with this medicine.
- If you experience signs or symptoms of bleeding, consult your doctor immediately.
- Tell your doctor immediately if you are unable to stop any bleeding after a fall or injury, especially if you hit your head.

1. What is this medicine intended for?

- Preventing and treating blood coagulation.

Therapeutic group:

Vitamin K antagonists.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient (warfarin sodium) or to any of the other ingredients of this medicine (listed in section 6).
- you are pregnant, may become pregnant or gave birth within the last 48 hours.

- you have or have ever had any bleeding problems.
- you recently had a stroke caused by bleeding in the brain.
- you had surgery within the last 72 hours or are going to have surgery within the next 72 hours.
- you are taking medicines that, when taken together with Coumadin, may increase the risk of bleeding (see section: 'Drug interactions').

If any of these conditions applies to you, do not take this medicine and go back to your doctor to discuss your treatment.

Special warnings about using this medicine

- Take vitamin K supplements only if they were prescribed by doctors, because a sudden increase in vitamin K intake may reduce the effect of warfarin.
- Keep your doctor informed about every aspect of your health; because flu or feeling unwell may increase this medicine's effect, while a stomach upset, diarrhea and vomiting may reduce the effect of the medicine.

Before using Coumadin, tell your doctor if:

- you have very high blood pressure that is not controlled by medicines.
- you have or have ever had a stomach or duodenal ulcer.
- you previously had gastrointestinal bleeding.
- you recently had an ischemic stroke (caused by blockage of the blood vessels in the brain).
- you have a bacterial infection of the heart lining (endocarditis).
- you have problems with blood circulation to the brain (cerebrovascular disease).
- you have thyroid problems.
- you have severe heart disease, liver or kidney problems.
- you have a health condition making you prone to blood clots (thrombophilia).
- you have anemia (low hemoglobin level causing extreme tiredness, breathlessness and poor resistance to infections).
- you have a tumor or cancer.
- you were recently bruised or injured.
- you are at a higher risk of bleeding, for example, if you are over 65 years old or are unsteady on your feet and more likely to fall and injure yourself.

If any of these conditions apply to you, tell your doctor or pharmacist before you start taking Coumadin, because you may need to be checked more often during treatment.

Always tell your doctor, surgeon, nurse, dentist or pharmacist that you are taking Coumadin (warfarin).

Surgery

Due to the risk of bleeding, you may need to have your dosage lowered before surgery or a tooth extraction. Stop taking Coumadin (warfarin) 72 hours before and after surgery where there is a risk of severe bleeding. Tell your doctor or dentist that you are taking warfarin.

Smoking

Consult your doctor if you decide to give up smoking because giving up smoking may increase the effect of the medicine.

Tests and follow-up

During the course of treatment with this medicine, you will need to have regular tests for blood coagulation. These blood tests are very important in order to make sure that you are

taking the correct dosage. You will have these blood tests more frequently if your dosage is changed, if you start or stop using other medicines, or if you have liver or kidney problems.

Drug interactions

If you are taking or have recently taken any other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

Do not take this medicine, and tell your doctor if you are taking the following medicines:

alteplase, reteplase, streptokinase, tenecteplase, urokinase (fibrinolytic medicines for treating or preventing blood clots); St. John's Wort (*hypericum perforatum*) - a herbal remedy for depression.

Tell your doctor before you start taking the following medicines:

non-steroidal anti-inflammatory drugs (NSAIDs) for pain and inflammation, including aspirin, ibuprofen, celecoxib, diclofenac, indomethacin, meloxicam; clopidogrel, abciximab, dipyridamole, eptifibatide, tirofiban (antiplatelet medicines to prevent or breakdown blood clots); heparin or medicines containing heparin, bivalirudin, fondaparinux, dabigatran, rivaroxaban, danaparoid, prostacyclin (other anticoagulants); sulfapyrazone (for treatment of gout); glucosamine (for treatment of osteoarthritis); SSRI and SNRI anti-depressants such as citalopram, fluoxetine, paroxetine, venlafaxine; some types of medicines used to prevent blood clotting (such as warfarin, dicoumarol, phenprocoumon, acenocoumarol and fluindione). The effect of these medicines may be stronger when taken with glucosamine. Patients who take such combinations should be monitored with special care when initiating or ending glucosamine therapy.

Medicines that increase the effect of this medicine: tell your doctor if you are taking:

prolonged, regular use of paracetamol (for pain or inflammation); antibiotics, such as amoxicillin, levofloxacin, and tetracycline; allopurinol (for gout); capecitabine, erlotinib, tamoxifen (for types of cancer); disulfiram (for alcohol dependence); ketoconazole, fluconazole, itraconazole (for fungal infections); omeprazole (for stomach ulcers); propafenone, amiodarone, quinidine (for heart disorders); methylphenidate (for attention deficit disorders); zafirlukast (for asthma); bezafibrate, ciprofibrate, fenofibrate, gemfibrozil (to reduce blood fats); statins such as fluvastatin to lower cholesterol (not including pravastatin); erythromycin, sulfamethoxazole, metronidazole (for bacterial infections); orlistat (for obesity).

Medicines that reduce the effect of this medicine: tell your doctor if you are taking:

barbiturates (sedatives); primidone, phenytoin, carbamazepine (to treat epilepsy); griseofulvin (for fungal infections); oral contraceptives; rifampicin (for tuberculosis); azathioprine (for inflammatory bowel disease and rheumatoid arthritis and to prevent organ rejection); sucralfate (for stomach ulcers); cholestyramine (for lowering cholesterol); vitamin K (increased consumption of vitamin K may reduce the effect of warfarin).

Medicines that have varying effects on this medicine: tell your doctor if you are taking:

corticosteroids (for inflammations and many other diseases); nevirapine, ritonavir (for HIV infection).

Using this medicine and food

Certain foods may affect how well Coumadin treatment works. During treatment with Coumadin you are required to maintain a regular and balanced diet, keep your level of activity as close to normal as possible and avoid weight-reducing diets. Consult your doctor before any change in your diet. Food products such as liver, broccoli, brussels sprouts and green leafy vegetables contain a large amount of vitamin K. Excess vitamin K may reduce the effect of Coumadin. Do not make major changes in your diet during treatment with warfarin.

Refrain from drinking cranberry or grapefruit juice or taking cranberry products. These may increase the effect of the medicine.

Using this medicine and alcohol consumption

Do not drink large amounts of alcohol during treatment with warfarin. Acute consumption of a large amount of alcohol can inhibit the metabolism of warfarin and raise your INR.

Conversely, chronic heavy consumption of alcohol may increase the metabolism of warfarin.

Pregnancy, breastfeeding and fertility

Do not use this medicine if you are pregnant, may become pregnant or gave birth within the last 48 hours. Consult your doctor immediately if you get pregnant while using this medicine. If you are breastfeeding, it is unlikely that the medicine will harm your baby as long as you are taking the correct dosage.

Driving and using machines

This medicine has no known effect on the ability to drive or to operate machines.

Important information about some of this medicine's ingredients

This medicine contains lactose (a type of sugar). If you have been told that you have an intolerance to certain sugars, tell your doctor before you start using this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and treatment regimen.

Your dosage depends on the results of the blood tests carried out to measure the time it takes for your blood to clot. Be sure to take the dose at the same time every day.

Do not exceed the recommended dose.

Do not chew! Swallow the medicine with water. Do not keep the medicine in your mouth longer than the time it takes to swallow it. If your prescribed dose is half a tablet, split the tablet using a tablet-splitting device.

If you have taken an overdose or if a child has accidentally swallowed some of the medicine, go immediately to a doctor or to a hospital emergency room and bring the medicine package with you. Symptoms of overdose include bleeding, black tarry stools, blood in urine, heavy or continuous bleeding from cuts or wounds or unusually heavy menstrual bleeding.

If you forget to take this medicine

If you usually take this medicine in the evening and you forget to take the medicine, if you remember before midnight on the same day, take the forgotten dose. If midnight has passed, do not take the forgotten dose. Take your normal dose the next day at the usual time.

If you usually take this medicine in the morning and you forget to take it, take the medicine as soon as you remember and continue with the regular schedule.

But if it is already time to take your next dose, do not take the forgotten dose. Never take a double dose to compensate for a forgotten one!

Make a note for yourself that you missed a dose. If you are not sure what to do if you forgot a dose, ask your doctor.

Adhere to the treatment as recommended by your doctor. Even if your health improves, do not stop taking this medicine without consulting with your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, use of Coumadin may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop using this medicine and go to the hospital immediately if:

You experience a rare allergic reaction, such as swelling of the face, tongue, lips and throat, difficulty breathing, severe itching of your skin with raised lumps. You may need urgent medical attention.

Consult your doctor immediately if the following appear (the frequency of these effects is not known):

unexpected bleeding or signs of bleeding (this could mean that your clotting values are too low and that your dosage needs to be adjusted): unexplained nose bleeds or bleeding of the gums, bruising or red spots on your skin for no apparent reason, heavy or continuous bleeding from wounds and cuts, pink, dark red or brown urine (this may be due to bleeding in the bladder or kidneys), black tarry stools, vomiting of blood or particles that look like coffee grounds (signs of bleeding in the stomach or intestines), bleeding from the rectum, coughing up blood, (in women) unusually heavy menstrual bleeding or bleeding from the vagina; blurred vision, slurred speech, loss of movement, numbness, dizziness, headache, nausea or vomiting, spasms, loss of consciousness, which may be signs of bleeding in the brain; painful, blue-purple colored toes; yellowing of the skin and white of the eye (jaundice); severe pain in the upper abdomen (a sign of inflammation of the pancreas); painful skin rash. In rare cases, warfarin may cause serious skin effects, including an effect known as calciphylaxis, which can start as a painful skin rash, but may lead to other serious complications. This side effect occurs more frequently in patients with chronic kidney disease.

If any of the following side effects persists, gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor or pharmacist:

nausea or vomiting, diarrhea, hair loss, skin rash, fever, sharp drop in the number of red blood cells or in the blood hemoglobin level (shown in blood tests).

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor!

Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: Store below 25°C.

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

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose anhydrous, pregelatinized starch, magnesium stearate, color lakes (**1 mg**: D&C Red No. 6, barium lake, **2 mg**: FD&C Red No. 40 lake, FD&C Blue No. 2 lake, **2.5 mg**: D&C Yellow No. 10 lake, FD&C Blue No. 2 lake, **5 mg**: D&C Yellow No. 10 lake, D&C Red No. 6 barium lake).

What the medicine looks like and contents of the pack:

Plastic bottle with a child-proof cap. Each package contains 30/100/1,000 tablets.

Not all pack sizes may be marketed.

Tablet appearance:

Coumadin 1 mg – flat, pink, capsule-shaped tablet, debossed with TARO WARFARIN on one side and a score line and the numeral “1” on the other side.

Coumadin 2 mg – flat, lavender, capsule-shaped tablet, debossed with TARO WARFARIN on one side and a score line and the numeral “2” on the other side.

Coumadin 2.5 mg – flat, green, capsule-shaped tablet, debossed with TARO WARFARIN on one side and a score line and the numeral “2½” on the other side.

Coumadin 5 mg – flat, peach, capsule-shaped tablets, debossed with TARO WARFARIN on one side and a score line and the numeral “5” on the other side.

Name and address of the manufacturer and registration-holder:

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

Registration number of the medicine in the Ministry of Health National Drug Registry:

Coumadin 1 mg tablets: 111.43.29373

Coumadin 2 mg tablets: 111.44.29374

Coumadin 2.5 mg tablets: 111.45.29375

Coumadin 5 mg tablets: 111.48.29378

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