

**Warfarin 1 mg, 3 mg and
5 mg Tablets**
warfarin sodium

Package leaflet: Information for the user

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 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 symptoms 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.
- It is important to take the correct dose. If you have difficulty, ask someone to help you. If you take the wrong dose or take too much, contact your doctor or pharmacist (see section 3).
- Carry your Warfarin record card with you at ALL times. Always tell any doctors, surgeons, nurses, dentists or pharmacists that you are taking Warfarin.
- Warfarin can be affected by many other medicines including non-prescription medicines, herbal remedies, vitamin and food supplements. (See section 2 'Other medicines and Warfarin'). Do not start taking any new medicine without checking it is safe to take it with Warfarin; especially aspirin, ibuprofen and other NSAIDs (non-steroidal anti-inflammatory medicines), as these can make you more likely to bleed.
- Some foods and illnesses can affect Warfarin treatment. Follow the advice in section 2 'Things which affect Warfarin'.
- If you have any signs or symptoms of bleeding, contact a doctor straight away (see section 4).
- Seek medical help at once if you are unable to stop any bleeding, you fall, get hurt or hit your head.

What is in this leaflet

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

1 What Warfarin is and what it is used for

Warfarin belongs to a group of medicines called anticoagulants. It is used to reduce the clotting ability of the blood. (It is sometimes called a 'blood thinner', but it does not actually thin the blood.)

Warfarin is used to prevent and treat blood clots forming in the legs, lungs, brain and heart.

The tablets come in three strengths and colours: 1 mg (brown); 3 mg (blue); 5 mg (pink).

2 What you need to know before you take Warfarin

Do not take Warfarin

- if you are **allergic** to Warfarin or any of the other ingredients of this medicine (listed in section 6).
- if you are **pregnant** in the first trimester and the last four weeks of pregnancy or may become pregnant or have had a **baby in the last 48 hours**
- if you have a **severe bleeding**
- if you have or have ever had any **bleeding problems**
- if you have recently had a **stroke** caused by bleeding in the brain
- if you have had **surgery** within the last 72 hours or are going to have surgery in the next 72 hours
- if you have a **serious risk of bleeding** (for risk factors see 'Warnings and precautions')
- in the case of **severe liver disease**
- if you are taking natural medicines containing St John's wort (*Hypericum perforatum*), non-steroidal anti-inflammatory drugs (**NSAIDs**), **aspirin** or **anti-clotting medicines** as this may increase the risk of bleeding. (See section 2 'Other medicines and Warfarin').

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Warfarin

- if you have very **high blood pressure** which is not controlled by medicines
- if you have a **stomach** or **duodenal ulcer** or have ever had one
- if you previously had **gastrointestinal, urogenital or respiratory bleeding**
- if you had recent **ischaemic stroke** (caused by blockage of blood vessels in the brain)
- if you have an **infection of the heart lining** (bacterial endocarditis)
- if you have problems with **circulation of blood to the brain** (cerebrovascular disease)
- if you have **thyroid** problems
- if you have severe **heart disease, liver or kidney** problems
- if you have a condition making you **prone to blood clots** (thrombophilia)
- if you have **anaemia** (low haemoglobin causing extreme tiredness, breathlessness, poor resistance to infection)
- if you have a **tumour or cancer**
- if you had a recent **wound or injury**
- if you have **oesophageal varices or arterial aneurysm**
- if you have **protein C or protein S deficiency** (disorders that can cause an increased risk of blood clots).
- if you have a higher risk of bleeding, for example because you are over 65 years of age or are unsteady on your feet and more likely to fall and injure yourself.

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

Regular blood tests

You will have regular blood tests to see how long it takes your blood to clot. These blood tests are very important to make sure you are taking the right dose. Blood tests will be more frequent if you have had your dose of Warfarin changed, if you have started or stopped taking other medicines, or have liver or kidney problems.

Things which affect Warfarin

A number of things affect blood clotting and can therefore affect your Warfarin treatment. To make sure your Warfarin works properly and safely, it is important to follow the advice below.

Increases effect of Warfarin	Reduces effect of Warfarin	What to do
Weight loss	Weight gain	Do not go on a weight reducing diet or change your eating habits without discussing it first with your doctor or nurse. Keep your level of activity as close to normal as possible.
	Vitamin K	Do not take vitamin K supplements.
	Foods such as liver, broccoli, brussel sprouts and green leafy vegetables contain large amounts of vitamin K.	Don't make any major changes to your diet whilst taking Warfarin.
Cranberry juice and cranberry products (and possibly grapefruit juice)		Don't drink either cranberry juice or grapefruit juice or products containing these whilst taking Warfarin.
Large amounts of alcohol		Only drink small amounts whilst taking Warfarin.
Sudden illness such as the flu or feeling run down	Stomach upset, diarrhoea, being sick (vomiting).	If any of these happen, tell your doctor or nurse, as your dose may need to be changed.
Stopping smoking		Seek medical advice before you give up smoking.

Keep healthcare professionals informed

Carry your anticoagulation record card with you at ALL times. Always tell any doctors, surgeons, nurses, dentists or pharmacists that you go to that you are taking Warfarin. You should also have received a booklet which includes more information about Warfarin along with a list of symptoms which need to be checked by your doctor immediately.

Operations

Due to the risk of bleeding, you may need to lower your dose before an operation or removal of teeth. You should stop taking Warfarin 72 hours before and after surgery where there is a risk of severe bleeding. Make sure you tell your doctor or dentist you are taking Warfarin.

Other medicines and Warfarin

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines including over the counter medicines, herbal remedies and vitamin supplements.

Do not take Warfarin and tell your doctor if you are taking:

- alteplase, reteplase, streptokinase, tenecteplase, urokinase (fibrinolytic drugs to treat or prevent blood clots)
- St John's wort (*Hypericum perforatum*) a herbal remedy for depression.

Check with your doctor first before taking these medicines:

- non-steroidal anti-inflammatory drugs (NSAIDs) for pain and inflammation including aspirin, ibuprofen, celecoxib, diclofenac, indometacin, meloxicam, phenylbutazone
- clopidogrel, abciximab, dipyridamole, eptifibatide, tirofiban (antiplatelet drugs to prevent or break down blood clots)
- heparin or medicines containing heparin, bivalirudin, fondaparinux, dabigatran, rivaroxaban, danaparoid, prostacyclin (other anticoagulants)
- sulfipyrazone (for gout)
- glucosamine (for osteoarthritis)
- SSRI and SNRI antidepressants such as citalopram, fluoxetine, paroxetine, venlafaxine.

Medicines which increase the effect of Warfarin

Tell your doctor if you are taking

- prolonged, regular use of paracetamol (for pain or inflammation)
- antibiotics such as amoxicillin, levofloxacin and tetracycline
- erythromycin, sulfamethoxazole, metronidazole (for bacterial infections)
- allopurinol (for gout)
- capecitabine, erlotinib, imatinib, fluorouracil, tamoxifen (for types of cancer)
- disulfiram (for alcohol dependence)
- ketoconazole, fluconazole, itraconazole,

- voriconazole (for fungal infections)
- proton pump blockers such as omeprazole (for stomach ulcers)
- propafenone, amiodarone (for heart disorders)
- methylphenidate (for attention deficit disorder)
- zafirlukast (for asthma)
- bezafibrate, ciprofibrate, fenofibrate, gemfibrozil (to reduce high blood fats)
- statins such as simvastatin or fluvastatin to lower cholesterol (but this does not include pravastatin)
- orlistat (for obesity).

Medicines which decrease the effect of Warfarin Tell your doctor or pharmacist if you are taking

- barbiturates (sedatives)
- primidone, phenytoin, carbamazepine (to treat epilepsy)
- griseofulvin (for fungal infections)
- oral contraceptives (the 'Pill')
- rifampicin (for tuberculosis)
- azathioprine (for inflammatory bowel disease and rheumatoid arthritis and to prevent organ rejection)
- sucralfate (for stomach ulcers)
- colestyramine (for lowering cholesterol).

Medicines which have varying effects on Warfarin Tell your doctor or pharmacist if you are taking

- corticosteroids (for inflammation and many other diseases)
- nevirapine, ritonavir (for HIV infection).

Many other medicines alter the treatment effect of Warfarin, which means that it may be necessary to adjust the dosage or observe other safety precautions when Warfarin is taken at the same time as a series of other drugs. It is therefore important that the treating doctor be informed of all other medication that is being taken at the same time.

Warfarin with food and drink

Cranberry should be avoided during treatment with Warfarin.

The daily intake of vitamin K-rich foods such as cabbage, broccoli, spinach and avocado should be as even as possible. Changes in the amount of vitamin K in the diet can alter the effect of Warfarin. Alcohol can alter the effect of Warfarin.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, may become pregnant or have had a baby within the last 48 hours.

See your doctor straight away if you get pregnant whilst taking this medicine.

Warfarin is unlikely to harm your baby during breast-feeding, if taken at the correct dose.

Driving and using machines

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

Warfarin contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Warfarin contains sodium

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

3 How to take Warfarin

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

Your dose will be decided by your doctor and will depend on the results of the blood tests carried out to measure the time it takes your blood to clot.

The entire dose should be taken at the same time each day.

If you take more Warfarin than you should

Talk to your doctor or go to your nearest hospital casualty department straight away. Take the medicine pack with you. Symptoms of taking too much Warfarin include bleeding, black tarry stools, blood in urine, heavy bleeding or oozing from cuts and wounds or unusually heavy menstrual bleeding.

If you forget to take Warfarin

If you usually take your Warfarin in the evening and you have forgotten to take it, if you remember before midnight on the same day, take the missed dose. If midnight has passed do not take that dose. Make a note that you have missed a dose and take your normal dose the next day at the usual time.

If you usually take your Warfarin in the morning and have forgotten to take it the general advice is as follows:

- if it is less than two hours late, take the dose as soon as you remember and then continue as normal.
- if it is more than two hours late, take the dose as soon as you remember and then continue as normal. However, if it is time to take your next dose leave out the missed dose. Never take a double dose to catch up. Make a note that you have missed a dose.

If you are not sure what to do if you have missed a dose ask your GP or anticoagulant clinic for advice.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Do not be concerned about this list of side effects. You may not get any of them, but it is important to know what to do if they occur.

Stop taking Warfarin and go to hospital at once if you have:

- 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.

If any of the following occur, stop taking the tablets and tell your doctor immediately:

If you fall or injure yourself during treatment, especially if you hit your head. Please seek urgent

medical attention. You may need to be checked by a doctor, as you may be at increased risk of bleeding.

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.

Very common (may affect more than 1 in 10 people):

- bleeding from different organs.

Always contact your doctor if you develop bleeding.

Common (may affect up to 1 in 10 people):

- increased sensitivity to warfarin following long-term treatment.

Uncommon (may affect up to 1 in 100 people):

- anaemia,
- vomiting, nausea, diarrhoea.

Rare (may affect up to 1 in 1,000 people):

- impaired liver function, jaundice,
- skin rash, nettle rash, itching, hair loss, local inflammation of blood vessels in the skin, tissue damage, tissue damage in the skin

Very rare (may affect up to 1 in 10,000 people):

- hypersensitivity reactions,
- blue toe syndrome (painful, blueish discolouration of the toes),
- dark-coloured or black stools.

Not known (may affect an unknown number of people):

- fever
- blurred vision, slurred speech, loss of movement, numbness, dizziness, headache, confusion, feeling or being sick, fits, loss of consciousness. These could be a sign of a bleed in the brain.
- bleeding
- coughing up blood, nose bleed
- gastrointestinal bleeding, bleeding from the back passage (rectum), vomiting blood, severe pain in the upper abdomen (a sign of inflammation of the pancreas), abdominal pain (due to bleeding)
- accumulation of calcium in the blood vessel walls (leading to increasing and painful skin ulcers), purple patches like bruising, red swollen skin patches leading to bruise like areas,
- pink, dark red or brown urine (this may be due to bleeding in the bladder or kidneys), impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy);
- unexplained drop in red blood cells (haematocrit), decrease of haemoglobin (the protein in red blood cells that carries oxygen around the body).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Warfarin

Keep out of the sight and reach of children.

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

Do not store above 25°C. Store in the original package.

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

6 Contents of the pack and other information

What Warfarin contains:

- The active ingredient is warfarin sodium. Each tablet contains 1 mg warfarin sodium. Each tablet contains 3 mg warfarin sodium. Each tablet contains 5 mg warfarin sodium.
- The other ingredients are lactose monohydrate, maize starch, pregelatinised starch (maize), sodium starch glycolate type A, magnesium stearate, purified water, indigo carmine (E132) (1 mg and 3 mg), yellow iron oxide (E172) (1 mg), red iron oxide (E172) (1 mg), erythrosine (E127) (5 mg), aluminium oxide.

What Warfarin looks like and contents of the pack

- Warfarin 1 mg Tablets (diameter 8 mm) are brown with WFN above and 1 below a breakline on one side and twin triangle on reverse.
- Warfarin 3 mg Tablets (diameter 8 mm) are blue with WFN above and 3 below a breakline on one side and twin triangle on reverse.
- Warfarin 5 mg Tablets (diameter 8 mm) are pink with WFN above and 5 below a breakline on one side and twin triangle on reverse.

Warfarin Tablets are available in packs of 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 500, and in hospital packs of 10,000 and 100,000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer

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