

Package leaflet: Information for the user**WARFARIN 1 MG, 3 MG OR 5 MG TABLETS**
Warfarin Sodium**Read all of this leaflet carefully before you start using 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- It is important to take the correct dose. If you have difficulty, ask someone to help you. If you take the wrong dose or 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 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 Tablets**’). 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 drugs), as these can make you more likely to bleed.
- Some foods and illness 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 or straight away (See Section 4).
- Seek medical help at once if you unable to stop any bleeding, you fall, get hurt or hit your head.

What is in this leaflet:

1. What Warfarin Tablets are and what they are used for
2. What you need to know before you take Warfarin Tablets
3. How to take Warfarin Tablets
4. Possible Side Effects
5. How to store Warfarin tablets
6. Contents of the pack and other information

1. What Warfarin Tablets are and what they are 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.

2. What you need to know before you take Warfarin Tablets**Do not take these tablets if you:**

- are **allergic** to warfarin or to any of the other ingredients (listed in section 6)
- are **pregnant** (especially during first and last three months of pregnancy) or may become pregnant or have had a **baby in the last 48 hours**
- have or have ever had any **bleeding problems**
- have recently had a **stroke** caused by bleeding in the brain
- have had **surgery** within the last 72 hours or are going to have surgery in the next 72 hours
- are taking 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 Tablets’).

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 or nurse before taking warfarin to check if any of the following apply to you. You may need to be more closely monitored by your doctor if:

- you are an older person (over 65) or are unsteady on your feet and more likely to fall and injure yourself
- you drink large amounts of alcohol
- you have diarrhoea and are being sick
- you have any sudden illness or have recently been ill (such as having the flu or feeling run down)
- you have raised blood pressure that is not controlled by medicines
- you have liver or kidney problems
- you have a **stomach or duodenal ulcer** or have ever had one
- you previously had gastrointestinal bleeding
- you had recent ischaemic stroke (caused by blockage of blood vessels in the brain)
- you have a condition making you prone to blood clots (thrombophilia)
- anaemia (low haemoglobin causing extreme tiredness, breathlessness, poor resistance to infection)
- you have had a stroke
- you have an infection of the lining of your heart (bacterial endocarditis)
- bruise easily or have an illness that causes bleeding
- you have heart disease including congestive heart failure
- you have problems with circulation of blood to the brain (cerebrovascular disease)
- you have a tumour or cancer
- you have thyroid problems
- you have low vitamin K levels
- you have low levels of a substance called “Protein C” or “Protein S”. These stop blood clotting
- you take part in sports activities, particularly those with a high risk of injury or falling
- you are taking any medicines that may increase your risk of bleeding such as NSAIDS e.g. aspirin or other medicines that stop the blood from clotting
- you are going to have surgery. The doctor may have to change your dose or stop your warfarin treatment
- you are changing your diet or have recently lost or gained a lot of weight. Keep your diet and level of activity as close to normal as possible (please see Section 2 “Things which affect warfarin” for more information). This is because making changes in your diet may affect how your body responds to warfarin.

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	Vitamin K supplements should be taken only if prescribed by doctors as sudden increase in Vitamin K intake may decrease the effect of Warfarin
	Foods such as liver, broccoli, Brussels 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 grape fruit juice)		Don’t drink either cranberry juice or grapefruit juice or products containing these whilst taking warfarin. This is because cranberry may increase the effects of warfarin and cause bleeding. If you have been advised to have cranberry products for medical reasons (such as bladder infections), talk to your doctor or pharmacist before taking this medicine. They may ask you to stop using or reduce the amount of cranberry or monitor you more often while you are 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 your doctor or pharmacist 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 Tablets

Many medicines affect the way warfarin works. Tell your doctor or pharmacist if you are

taking, have recently taken or might take 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 any of the following medicines:

- non steroidal anti inflammatory drugs (NSAIDs) for pain and inflammation including aspirin, ibuprofen, celecoxib, diclofenac, indometacin, meloxicam
- other medicines used to thin your blood (anticoagulants) or stop clotting such as clopidogrel, dipyridamole, dabigatran, bivalirudin, heparins, fondaparinux, rivaroxaban, eptifibatide, tirofiban, abciximab and prostacyclin. If you are changing to warfarin from another anticoagulant you should tell your doctor.
- medicines to treat depressions such as SSRIs (selective serotonin reuptake inhibitors), for example, fluoxetine and citalopram or SNRIs (serotonin norepinephrine reuptake inhibitors) such as venlafaxine
- alteplase, reteplase, streptokinase, tenecteplase, urokinase (fibrinolytic drugs to treat or prevent blood clots)
- glucosamine (for osteoarthritis)
- SSRI and SNRI anti depressants such as citalopram, fluoxetine, paroxetine, venlafaxine
- Some types of medicines used to prevent blood clotting (e.g. warfarin, dicoumarol, phenprocoumon, acenocoumarol and fluidione). The effect of these medicines may be stronger when used with glucosamine. Patients treated with such combinations should therefore be monitored extra carefully when initiating or ending glucosamine therapy.
- sulfapyrazone – used for gout
- St. John’s Wort (Hypericum perforatum) - a herbal remedy used for depression.

The following medicines may increase the effect of your warfarin:

- medicines for gout, pain and inflammation called non-steroidal anti inflammatory drugs (NSAIDs) such as aspirin, indometacin, celecoxib
- medicines for heart problems such as amiodarone, propafenone, propranolol or quinidine
- medicines that reduce high levels of fats (lipids) in your blood such as bezafibrate or gemfibrozil or lower your cholesterol levels such as fluvastatin
- colestyramine - used for itching and diarrhoea in some illnesses
- medicines to help you sleep such as chloral hydrate or triclofos which relax your muscles
- anabolic steroids such as stanozolol or corticosteroids such as hydrocortisone
- medicines for pain and inflammation in illnesses like rheumatism and arthritis such as paracetamol, allopurinol or phenylbutazone
- antibiotics such as amoxicillin, levofloxacin and tetracycline
- medicines for infection such as cefamandole, chloramphenicol, ciprofloxacin, cotrimoxazole, erythromycin, clarithromycin, metronidazole, levofloxacin, neomycin, sulfamethoxazole or tetracyclines
- medicines for fungal infections such as fluconazole or ketoconazole
- medicines for diabetes such as glibenclamide
- medicines for thyroid problems
- medicines for asthma such as zafirlukast
- cimetidine, omeprazole – used for stomach ulcers or too much stomach acid
- statins such as fluvastatin to lower cholesterol (but this does not include pravastatin)
- orlistat (for obesity)
- tamoxifen, capecitabine, erlotinib - used to treat cancer
- danazol - used for menstrual problems or endometriosis
- methylphenidate - used for hyperactivity disorder
- disulfiram - used for alcohol addiction
- dextropropoxyphene – used for pain

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FLAT DIMENSION = 180 x 500mm

FOLDED DIMENSION = 180 x 31mm

- glucosamine- used for osteoarthritis

The following medicines may decrease the effect of your warfarin:

- medicines for epilepsy such as phenobarbital, phenytoin, primidone or carbamazepine
- barbiturates (sedatives)
- azathioprine (for inflammatory bowel disease and rheumatoid arthritis and to prevent organ rejection)
- rifampicin – used for infections like TB (tuberculosis)
- griseofulvin – used for fungal infections
- phenazone – used for pain
- oral contraceptives (the “pill”)
- aminogluthethimide - used for cancer
- flucloxacillin- used for bacterial infections
- spironolactone-used to pass water.
- sucralfate (for stomach ulcers)
- cholestyramine (for lowering cholesterol)
- vitamin K (an increase in the amount of your vitamin K intake could reduce the effect of Warfarin).

If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before taking warfarin.

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).

Warfarin Tablets with food, drink and alcohol:

Patients should seek medical advice before undertaking any major changes in diet while taking Warfarin Tablets. Patients should be advised to avoid cranberry products. Acute ingestion of a large amount of alcohol may inhibit the metabolism of warfarin and increase INR. Conversely, chronic heavy alcohol intake may induce the metabolism of warfarin.

Pregnancy and breast-feeding

- Do not take this medicine if you are pregnant (especially during first and last three months of pregnancy), 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 breastfeeding, if taken at the correct dose.

Driving and using machines

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

Warfarin tablets contain Lactose and Sucrose

- If you have been previously told by your doctor that you have intolerance to some sugars (such as lactose or sucrose), contact your doctor before taking this medicine.

Information on sodium content:

Warfarin tablets contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Warfarin Tablets

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

The usual doses are given below. The correct dose will be decided by your doctor based on your response (INR) to the medicine. Follow your doctor’s instructions carefully.

Adults

- On days one and two, the usual starting dose is 10mg (10ml), taken at the same time each day
- On days 3 and onwards, the usual dose is 3mg to 9mg (3ml to 9ml), taken at the same time each day
- If you are an older person (over 65) your doctor may give you a lower dose.

Children

Warfarin is not recommended for use in children.

Blood tests

Your doctor will do blood tests during your treatment and may change your dose depending on the results.

If you take more warfarin than you should

If you take more of this medicine than you should, talk to a doctor or go to your nearest hospital straight away. Take the medicine pack with you.

If you forget to take warfarin

- If you forget a dose and remember within two or three hours, you can still take that dose.
- If you forget your dose for longer than three hours, do not take that dose. Instead, wait until the next dose is due.
- Do not take a double dose to make up for a forgotten dose.
- Tell your doctor that you have forgotten a dose when you next see them or when you have your blood test.

If you stop taking warfarin

Do not stop taking warfarin unless your doctor tells you to. It may be dangerous to do so. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, warfarin 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 see a doctor or go to a hospital straight away if you notice the following serious side effect- you may need urgent medical treatment:

- Allergic reaction** - the signs may include swelling of your face, lips, tongue or throat, difficulty breathing or swallowing, severe itching of your skin with raised lumps.

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 or go to a hospital straight away if you get any of the following side effects. Your doctor may decide to stop your warfarin treatment:

- Impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy) (frequency not known)
- 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.
- Any bleeding at all as this is a sign that your clotting levels are low:

Examples of bleeding that have been noted with the use of warfarin are:

- nose bleeds without any obvious reason
- loss of consciousness, fits, numbness, headache, dizziness, feeling or being sick, slurred speech, blurred vision. These could be signs that there is a bleed in your brain
- change in the colour of your urine - a dark red or brown urine might be due to bleeding in your kidneys or bladder
- heavy bleeding or oozing from cuts and wounds
- black tarry stools, vomiting blood or particles that look like coffee grounds (signs of bleeding in the stomach or intestines), bleeding from the back passage (rectum)
- coughing up blood
- severe pain in the upper abdomen (a sign of inflammation of the pancreas)
- red or purple swollen patches on your skin that look like bruises
- painful red patches of skin that have blood filled blisters that turn black
- feeling sick (nausea) or being sick (vomiting), fever, pain, swelling or tenderness in your stomach or back or difficulty in breathing and chest pain
- yellowing of the skin and whites of the eyes (jaundice)
- painful, blue-purple coloured toes

Tell your doctor or pharmacist if any of the following side effects persist, get worse or if you notice any other side effects not listed:

- hair loss
- skin rash.
- feeling sick or being sick, diarrhoea
- fever
- drop in number of red blood cells, blood haemoglobin (shown in blood tests).

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 Yellow Card Scheme Website: 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 Tablets

- Keep this medicine out of the sight and reach of children.
- Blisters and Containers: Do not store above 25°C. Store in the original package and keep the container tightly closed.
- Do not use this medicine after the expiry date which is stated on the carton. 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. Contents of the pack and other information

What Warfarin Tablets contain

- Warfarin Tablets come in three strengths. Each tablet contains 1 mg, 3mg or 5mg of the active ingredient Warfarin Sodium.
- The other ingredients in Warfarin 1mg, 3mg & 5mg tablets are: lactose monohydrate, maize starch, sucrose, pregelatinised starch, magnesium stearate
- Warfarin 1mg Tablets also contains: black iron oxide (E172), red iron oxide (E172) and yellow iron oxide (E172)
- Warfarin 3mg Tablets also contains: indigo carmine aluminium lake (E132)

- Warfarin 5mg Tablets also contains: erythrosine aluminium lake (E127)

What Warfarin Tablets look like and contents of the pack

Each strength has a separate colour to distinguish it from the others. Be sure you are taking the right tablet by checking the colour and strength.

- Warfarin 1mg tablets: Brown coloured, circular, flat, faced bevelled edged uncoated tablet with ‘1’ debossed on one side and ‘BL’ debossed on the other.
- Warfarin 3mg tablets: Blue coloured, circular, flat faced bevelled edged uncoated tablet with ‘3’ debossed on one side and ‘BL’ debossed on the other.
- Warfarin 5mg tablets: Pink coloured, circular, flat faced bevelled edged uncoated tablet with ‘5’ debossed on one side and ‘BL’ debossed on the other.
- The tablets are packaged in blister packs of 20, 28, 56 or 112 tablets or in bulk containers of 100 or 500 tablets. Not all pack sizes may be marketed.

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Warfarin 1 mg Tablets; PL 17907/0103

Warfarin 3 mg Tablets; PL 17907/0104

Warfarin 5 mg Tablets; PL 17907/0105

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