

Package leaflet: Information for the user

Warfarin 5 mg tablets

warfarin sodium

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Warfarin tablets are and what are they 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 are they 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 tablets are used to prevent and treat blood clots forming in the legs, lungs, brain and heart.

The tablets are pink in colour.

2. What you need to know before you take Warfarin tablets

Do not take Warfarin tablets if you

- are allergic to warfarin or to any of the other ingredients of this medicine (listed in section 6)
- are pregnant 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 before taking Warfarin tablets if you have:

- very high blood pressure which is not controlled by medicines
- a stomach or duodenal ulcer or have ever had one
- previously had gastrointestinal bleeding (bleeding in the stomach or intestines)
- had recent ischaemic stroke (caused by blockage of blood vessels in the brain)
- an infection of the heart lining (bacterial endocarditis)
- problems with circulation of blood to the brain (cerebrovascular disease)
- thyroid problems
- severe heart disease, liver or kidney problems
- have a condition making you prone to blood clots (thrombophilia)
- anaemia (low haemoglobin causing extreme tiredness, breathlessness, poor resistance to infection)
- a tumour or cancer
- had a recent wound or injury
- 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 tablets, 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 of this medicine. The blood tests will be more frequent if you have had your dose of Warfarin tablets changed, if you have started or stopped taking other medicines, or have liver or kidney problems.

Things that affect warfarin

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

Increases the effect of Warfarin tablets	Reduces the effect of Warfarin tablets	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	<i>Do not take vitamin K supplements.</i> <i>0.5 mg</i> Vitamin K supplements should be taken only if prescribed by doctors as sudden increase in vitamin K intake may decrease the effect of Warfarin tablets.
	Foods such as liver, broccoli, brussel sprouts and green leafy vegetables contain large amounts of vitamin K	Do not make any major changes to your diet whilst taking Warfarin tablets.
Cranberry juice and cranberry products (and possibly grapefruit juice)		Do not drink either cranberry juice or grapefruit juice or products containing these whilst taking Warfarin tablets.
Large amounts of alcohol		Only drink small amounts of alcohol whilst taking Warfarin tablets.
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 are taking Warfarin tablets. You should also have received a booklet which includes more information about Warfarin tablets 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 of this medicine before an operation or removal of teeth. You should stop taking Warfarin tablets 72 hours before and after surgery where there is a risk of severe bleeding. Make sure to tell your doctor or dentist that you are taking Warfarin tablets.

Other medicines and Warfarin tablets

Many medicines affect the way warfarin works. You must tell your doctor or pharmacist before you start taking any other medicines including over the counter medicines, herbal remedies and vitamin supplements.

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

- alteplase, reteplase, streptokinase, tenecteplase, urokinase - fibrinolytic medicines 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
- clopidogrel, abciximab, dipyridamole, eptifibatide, tirofiban (antiplatelet medicines to prevent or break down blood clots)
- heparin or medicines containing heparin, bivalirudin, fondaparinux, dabigatran, rivaroxaban, danaparoid, prostacyclin (other anticoagulants)
- sulfapyrazone (for gout)
- 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. 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.

Medicines that increase the effect of Warfarin tablets. 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 some 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 disorder)
- zafirlukast (for asthma)
- bezafibrate, ciprofibrate, fenofibrate, gemfibrozil (to reduce high blood fats)
- statins such as fluvastatin to lower cholesterol (but this does not include pravastatin)
- erythromycin, sulfamethoxazole, metronidazole (for bacterial infections)
- orlistat (for obesity).

120 x 600 mm

Front Side

Fonts used : Times New Roman
Size : Min. 9pt., Max. 12pt.

Technical & Non Printing Colours
Keyline

Pharma code position shall be changed depending upon folding dimension.

ARTWORK DETAIL LABEL

Product	Warfarin 5 mg tablets			
Buyer/Country	SPUK	Component	Pack Insert	
Dimension	120 x 600 mm	Pack	NA	
New Item Code	1047136	Old Item Code	1046498	
Colour Shades	 Black	No. of Colours	1	

Change Control No.	PC-TSG/2022/047 - Record Number: 333151	Artwork Version	3.0
Design/Style	Front & Back Printing. To be supplied in the folded size of 60 x 37.5 mm		
Substrate	40 GSM Bible Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartanator Requirements	NA		

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Medicines that decrease the effect of Warfarin tablets. 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)
- cholestyramine (for lowering cholesterol)
- vitamin K (in vitamin supplements or in cod liver oil)

Medicines that have varying effects on Warfarin tablets. 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

Do not consume large amounts of alcohol.
Seek medical advice before undertaking any major changes in your diet while taking Warfarin tablets. Avoid consuming cranberry products.

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 breastfeeding, if taken at the correct dose.

Driving and using machines

Warfarin tablets have no known effect on the ability to drive or operate machines

Warfarin tablets contain lactose

This medicine 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 tablets contain sodium

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

3. How to take Warfarin tablets

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.

Dose

Once you have been stabilised on this medicine the usual dose is between 3 - 9 mg once a day. Take the medicine at the same time each day, preferably on an empty stomach. The tablet can be divided into equal doses.

If you take more Warfarin tablets 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 many Warfarin tablets 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 tablets

If you usually take your Warfarin tablets in the evening and you have forgotten to take them, 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 tablets in morning and have forgotten to take them 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 taking the medicine as usual.
- if it is more than two hours late, take the dose as soon as you remember and then continue as usual. 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 doctor or anticoagulant clinic for advice.

4. Possible side effects

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

Stop taking this medicine 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.

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

- any unexpected bleeding or signs of bleeding (as this could mean that your clotting levels are too low and that your dose needs to be adjusted);
 - unexplained nose bleeds, bleeding gums
 - unexplained bruising or pinpoint red spots on your skin
 - heavy bleeding or oozing from cuts and wounds
 - pink, dark red or brown urine (this may be due to bleeding in the bladder or kidneys)
 - 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
 - (in women) unusually heavy periods or bleeding from the vagina
 - blurred vision, slurred speech, loss of movement, numbness, dizziness, headache, feeling or being sick, fits, loss of consciousness. These could be signs of a bleed in the brain.
- painful, blue-purple coloured toes
- yellowing of the skin and white of eyes (jaundice)
- severe pain in the upper abdomen (a sign of inflammation of the pancreas).
- 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.

Adverse effects with no known frequency: Impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy).

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.

- feeling sick or being sick, diarrhoea
- hair loss
- skin rash
- 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 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 tablets

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not take this medicine after the expiry date which is stated on the carton after EXP. 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

- The active substance is warfarin sodium. Each tablet contains warfarin sodium 5 mg.
- The other ingredients are: lactose monohydrate, maize starch, pregelatinized starch, sodium starch glycolate and magnesium stearate.
- Warfarin tablets contain Erythrosine aluminium Lake (E127) as the colourant.

What Warfarin tablets look like and contents of the pack

Warfarin 5 mg tablets are pink coloured, mottled, round, flat, bevel-edged, uncoated tablets of 2.30 ± 0.3 mm thickness, debossed as "S""576" divided by break line and plain on the other side.

PVC/PVDC/Alu -Blister Packs in pack sizes of 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Strides Pharma UK Ltd.
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Manufacturer

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Back Side

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