

Package leaflet: Information for the patient

FARIN Tablets

1 and 5 mg TABLETS

(Warfarin Tablets BP 1 and 5 mg)

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 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. See section 4.

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
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1. What Warfarin Tablets are and what they are used for

Warfarin Tablets belong to a group of drugs called anti-coagulants. You take Warfarin Tablets to help thin your blood if you have had a heart problem, problems with blood clots or your blood flow. You may also be given Warfarin Tablets if you have been fitted with a replacement heart valve.

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

Do not take Warfarin Tablets if you:

- are allergic to warfarin sodium or any of the other ingredients of this medicine (listed in section 6)
- are pregnant, breast-feeding or planning to become pregnant
- have problems with your liver or kidneys
- have had an infection of the lining of your heart
- have a condition which causes bleeding (such as a peptic ulcer) or makes you bruise easily
- have high blood pressure
- are taking the herbal remedy, St John's Wort (*Hypericum perforatum*) for depression

Do not take Warfarin Tablets within 24 hours of surgery or giving birth to a child.

Talk to your doctor if you:

- plan to have any surgery or a dental procedure. Tell all of your healthcare professionals and dentists that you are taking Warfarin Tablets. They should talk to the healthcare professional who prescribed Warfarin Tablets for you. This should be done before you have any surgery or dental procedure. Your Warfarin Tablets may need to be stopped for a short time or you may need your dose adjusted. Warfarin Tablets can affect your anaesthetic or cause bleeding
- lose weight, have an acute illness, have kidney problems or increase your intake of Vitamin K while taking Warfarin Tablets, as your dose may need to be changed (see section 3).

Other medicines and Warfarin Tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Many drugs may increase or decrease the effects of Warfarin Tablets. It is particularly important to tell your doctor if you are taking, or have recently taken any of the medicines listed below:

- drugs for heart problems (amiodarone, quinidine, propafenone)
- drugs for depression (amitriptyline, nortriptyline)
- Non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, aspirin, oxyphenbutazone, phenylbutazone and feprazone
- drugs to lower cholesterol in your blood (bezafibrate, gemfibrozil, clofibrate, cholestyramine)
- drugs to treat bacterial infections (aztreonam, cephmandole, co-trimoxazole, chloramphenicol, ciprofloxacin, erythromycin, metronidazole, nalidixic acid, neomycin, norfloxacin, rifampicin, sulphonamides, latamoxef, griseofulvin, tetracyclines and other broad spectrum antibiotics)
- drugs to treat fungal infections (miconazole, fluconazole, ketoconazole)
- drugs for pain and/or inflammation (paracetamol, azapropazone, diflunisal, extropropoxyphene, phenylramidol)
- cimetidine or sucralfate (stomach ulcers or acid) or omeprazole to reduce stomach acid
- danazol for menstrual problems
- drugs for diabetes (tolbutamide, glucagon, phenformin)
- salicylates used to treat ulcers
- allopurinol for gout
- tamoxifen for breast cancer or aminoglutethimide for breast or prostate cancer
- chloral hydrate or triclofos if you are having problems sleeping
- disilfram for alcoholism, oral contraceptives, anabolic steroids, corticosteroids, methylphenidate for hyperactivity, dipyridamole (to stop blood cells sticking together)
- drugs to treat thyroid problems
- carbamazepine, primidone or phenytoin for control of epilepsy
- vitamin K supplements
- sedatives such as barbiturates, ethchlorvynol or glutethimide
- the hormone ACTH, to treat a hormone deficiency or as part of a test requested by your doctor.

Do not take any other drug without speaking to your doctor first.

Warfarin Tablets with food, drink and alcohol

Do not drink large amounts of alcohol while taking Warfarin Tablets.

Drinking cranberry juice or taking other cranberry products (for example capsules or concentrates), might increase the effect of Warfarin Tablets in "thinning" the blood. You should therefore avoid drinking/taking these products whilst taking Warfarin Tablets. If you have been advised to take cranberry juice or other products for medical reasons (e.g. bladder infections), or are regularly drinking or taking cranberry products, you should contact your anticoagulant clinic or health advisor before making any changes to the amount you drink/take. Your doctor or clinic may wish to monitor you more frequently while you are taking any cranberry product.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Warfarin Tablets contain lactose

Warfarin Tablets 1 mg and 5 mg contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Warfarin Tablets 1 mg contain quinoline yellow (E104)

Warfarin Tablets 1 mg contain quinoline yellow (E104) which may cause allergic reactions.

Warfarin Tablets 5 mg contain erythrosine (E127)

Warfarin Tablets 5 mg contain erythrosine (E127) which may cause allergic reactions.

3. How to take Warfarin Tablets

Dosage

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will prescribe the dose of Warfarin Tablets that is right for you. Do not change your dose of Warfarin Tablets without talking to your doctor. Your doctor may test your blood while you are taking Warfarin Tablets.

Adults and the elderly (over 65 years):

The recommended dose is 10 mg daily for 2 days. Your doctor will do a blood test to decide the exact dose you should take. After the second day the recommended dose of Warfarin Tablets is between 3 and 9 mg once a day. Your doctor will tell you exactly how many Warfarin Tablets you should take. Try to take your tablets at the same time each day. Swallow the tablets or half tablets whole with water. The tablets can be divided into equal doses.

Use in children

No dose has been established for children.

If you take more Warfarin Tablets than you should

If you take too many tablets, or if you have unexplained bleeding, call your doctor or contact your nearest hospital immediately. Do not take more tablets than your doctor tells you to.

If you forget to take Warfarin Tablets

If you forget to take a dose at the right time, take it as soon as you remember unless it is nearly time for the next dose.

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

If you stop taking Warfarin Tablets

Do not stop taking the tablets unless told to do so by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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
- 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
- unexplained nose bleeds
- black or red faeces which may be caused by internal bleeding
- dark red or brown urine which may be caused by problems with your kidneys or bladder
- fever
- nausea and vomiting.

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.

If any of the following occur, call your doctor as soon as possible:

- allergic reaction
- skin rashes
- hair loss
- diarrhoea
- purple discolouration or 'bruising' to your skin
- a yellowing of your skin or whites of your eyes
- changes in the amount or colour of your urine.

Adverse effects with no known frequency:

- Impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy).

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. 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.

Do not store above 30°C. Protect from light.

Do not use 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 1 or 5 mg warfarin sodium.
- The other ingredients are lactose, pregelatinised maize starch and magnesium stearate

7. What Warfarin Tablets look like and contents of the pack

White, circular, flat, uncoated tablets having breakline on one side and other side is plain of each tablet.

28 tablets are packed in a poly bag and such poly bag is packed in a jar.

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Marketing Authorisation Holder and Manufacturer

AGOG PHARMA LTD.

Plot No. 33, Sector II, The Vasai Taluka Industrial Co-Op. Estate Ltd., Gauripada, Vasai (E), Dist. Thane, India.

180 mm

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82 mm