

Package leaflet: Information for the user

Warfant® 1mg, 3mg, 5mg 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.

This product will be referred to as Warfant Tablets from here on.

What is in this leaflet

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

1. What Warfant tablets are and what they are used for

The name of your medicine is Warfant 1mg, 3mg or 5mg Tablets and the active ingredient is warfarin sodium.

Warfarin belongs to a group of medicines called anticoagulants.

These medicines increase the time it takes for your blood to clot.

Warfarin is used to prevent and treat blood clots in the veins and arteries, for example clots in the lungs or heart.

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

Do not take Warfant Tablets:

- if you are allergic to warfarin sodium or any of the other ingredients of this medicine (listed in section 6).
- if you have had a stroke as a result of bleeding from a blood vessel in the brain
- if you are pregnant or planning to become pregnant or have just had a baby in the last 48 hours (please see the Section on “Pregnancy, breast-feeding and fertility”)
- if you have had surgery in the last 72 hours
- if you are taking medicines that may increase your risk of bleeding or other medicines that stop the blood from clotting
- if you suffer from unusual bruising or bleeding
- if you have a physical condition which might have a risk of bleeding such as recent stroke.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Warfant Tablets:

- if you are elderly (over 65 years)
- if you have recently lost or gained a lot of weight
- if you have any short term illness
- if you have recently quit smoking

- if you are suffering from vomiting or have diarrhoea
- if you are changing your diet, (vitamin K content may be different in different types of food and this may increase or decrease the effect of warfarin)
- if you have raised blood pressure that is not controlled by medicines
- if you have liver or kidney problems
- if you have an infection of the lining of your heart (bacterial endocarditis)
- if you have low levels of iron in the blood (which may lead to pale appearance of the eyes and skin)
- if you have heart disease and problems with circulation of blood to the brain (cerebrovascular disease)
- if you have a tumour or cancer
- if you have thyroid problems
- if you have ever had a stomach ulcer or bleeding in the stomach or intestines
- if you have low levels of a substance called “Protein C” or “Protein S”. These stop blood clotting
- if you have a high risk of injury or falling
- if you are taking any medicines that may increase your risk of bleeding or prevent blood clotting such as non-steroidal anti-inflammatories (NSAIDs) e.g. aspirin, ibuprofen
- if you are about to have surgery and doctor may have to change your dose or stop your warfarin treatment
- if you are using products that contain miconazole (including OTC products)
- if you observe signs of over-anticoagulation during treatment such as sudden unexplained bruising, nosebleeds or haematuria.

You should be given a ‘warfarin card’ (patient-held information booklet) at the start of treatment.

Children:

Do not give this medicine to children as it is unlikely to be safe.

Other medicines and Warfarin Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines because warfarin can affect the way some other medicines work or other medicines can affect the way warfarin works. If you are not sure, talk to your doctor or pharmacist.

- medicines used to thin your blood (anticoagulants) or stop clotting such as clopidogrel, dipyridamole, dabigatran, bivalirudin, heparins, fondaparinux, rivaroxaban, eptifibatide, tirofiban, abciximab, danaparoid and prostacyclin
- clot dissolving medications e.g. streptokinase, alteplase
- medicines for gout - sulfinpyrazone
- medicines for pain and inflammation - such as aspirin, indometacin, celecoxib
- medicines to treat depressions such as SSRIs (selective serotonin reuptake inhibitors), fluoxetine and citalopram or SNRIs (selective noradrenaline reuptake inhibitors) such as venlafaxine
- St. John’s Wort - a herbal remedy used for depression
- medicine used to treat allergic disorders like corticosteroids such as prednisolone
- medicines used to treat HIV - nevirapine, ritonavir
- medicines used to treat infections such as cefamandole, ciprofloxacin, co - trimoxazole, levofloxacin
- medicine used to help reduce weight - orlistat
- medicine used to treat itching and high levels of lipids (fats) in the blood - cholestyramine
- medicine used to treat stomach ulcers – sucralfate
- medicine used to treat arthritis - glucosamine
- vitamin K which can be found in vitamin supplements and enteral feeds
- medicine used to treat fungal infections-miconazole.
- 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.

The following medicines may increase the effect of your warfarin.

Tell your doctor or pharmacist if you are taking:

- medicines for heart problems such as amiodarone, propafenone
- medicines that reduce high levels of fats (lipids) in your blood such as bezafibrate or gemfibrozil or lower your cholesterol levels such as fluvastatin, clofibrate
- steroids such as zafirlukast
- medicines for pain and fever such as paracetamol
- medicine used to treat gout - allopurinol
- medicines used to treat infection such as erythromycin, metronidazole, sulfamethoxazole, chloramphenicol, moxifloxacin
- medicines for fungal infections such as azole anti fungals like fluconazole, ketoconazole, miconazole etc.
- medicines used for stomach ulcers or acidity e.g. cimetidine, omeprazole
- medicines used to treat cancer e.g. tamoxifen, capecitabine, erlotinib, gefitinib
- medicines used for hyperactivity disorder e.g. methylphenidate
- medicines for diabetes e.g. glibenclamide
- medicines used as diuretics e.g. acetazolamide
- anabolic steroids e.g. stanozolol
- medicines used for alcohol addiction - disulfiram.

The following medicines may decrease the effect of your warfarin.

- medicines for epilepsy such as phenobarbital, phenytoin, primidone or carbamazepine
- medicines for arthritis such as azathioprine
- medicine used in treatment of tuberculosis such as rifampicin
- medicine used for fungal infections such as griseofulvin
- medicine used for pain e.g. phenazone
- oral contraceptives (the “pill”), oestrogens
- Glutethimide (hypnotic sedative drug).

Warfant Tablets with food, drink and alcohol

- Avoid drinking grapefruit juice, cranberry juice or taking other cranberry products (for example capsules or concentrates), as they might increase the effect of Warfant Tablets in ‘thinning’ the blood. If you have been advised to take cranberry juice for medical reasons (e.g. bladder infections), or are regularly taking cranberry products/juice, you should contact your anticoagulant clinic or health advisor - they may wish to monitor you more frequently
- Do not drink large amounts of alcohol when taking Warfant Tablets
- Avoid making changes in your diet such as with foods which contain vitamin K such as liver and leafy green vegetables; as it may affect how your body responds to warfarin.

Pregnancy, breast-feeding and fertility

Warfant Tablets should not be taken if you are pregnant, planning to become pregnant or have had a baby in the last 48 hours. You should use a barrier method of contraception such as a condom. If you think that you may have become pregnant, contact your doctor as soon as possible. Warfant Tablets can have an adverse effect on the unborn child and alternative medicines are available. If considered necessary by your doctor, it may be possible to take Warfant Tablets whilst breast feeding. Speak to your doctor about this if it applies to you.

Driving and using machines

Warfant Tablets should not affect your ability to drive or use machines.

Warfant Tablets contain Lactose and Warfant 1 mg Tablets contain Azo colouring agents (dyes)-E102 and E123

This medicine contains lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Warfant 1mg Tablets contain azo colouring agents (dyes) E102 and E123 and they may cause allergic reactions. There are no azo colouring agents (dyes) in Warfant 3mg and 5mg Tablets.

Information on sodium content

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

3. How to take Warfant Tablets

Always take this medicine exactly as your doctor or pharmacist has told you.

Read the label on the container to see how many Warfant Tablets to take, and how often to take them.

Check with your doctor or pharmacist if you are not sure.

The recommended dose is

Adults

- Usual starting dose of 10mg daily for 2 days
- After 2 days the dose is usually changed to between 5mg and 12mg once a day; but can vary between 2mg and 30mg daily in some cases.

The doctor may vary your dose up or down depending on the results of a blood test which will be performed at the start and at regular intervals during your treatment.

Elderly

The dosage is likely to be less for the elderly.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

- Swallow the tablets whole with a drink of water
- Try to take the tablets at the same time each day
- Do not take more tablets than the doctor tells you to
- Do not stop taking your tablets except on your doctor’s advice as your condition may worsen.

Use in children

This product is not suitable for use in children.

If you have to go to another doctor, to hospital, or to a dentist, tell them that you are being treated with warfarin and ask them to contact your own doctor.

If you take more Warfant Tablets than you should

If you take too many Warfant Tablets, tell your doctor immediately or go to your nearest Hospital Casualty/Accident & Emergency Department. Take any remaining tablets and this leaflet with you so that the medical staff will know what you have taken.

If you forget to take your Warfant Tablets

- If you miss a dose and remember within two or three hours, you can still take that dose
 - If you forget for a longer time, do not take that dose to catch up, but take your next dose when it is due.
- Remember to tell your doctor when you see him/her next and have your blood test
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Warfant Tablets

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, pharmacist or nurse.

4. Possible side effects

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

Stop taking Warfant Tablets 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:

The following side effects have been reported but their frequency is not known:

- 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
 - Bleeding from any site 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 suggesting 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
 - black or red stools due to bleeding from the stomach, intestine or rectum
 - red or purple swollen patches on skin that look like bruises or painful red patches of skin with blood filled blisters that turn black
 - Fever
 - Vomiting of blood
 - Swelling or tenderness in your stomach or back
 - Difficulty in breathing and chest pain due to collection of blood in the chest
 - Yellowing of the skin and whites of the eyes (jaundice), problems with your liver
 - Purple painful toes
 - Unusual bruising more easily, getting more infections, feeling weak or tired more than usual. This is due to decreased blood cell count (your doctor will do tests to check this)
 - 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.
 - Impairment of renal function occurring with excessive anticoagulation and presence of blood in urine (anticoagulant-related nephropathy)
- If you get any of the above, please tell your doctor or go to hospital straight away.

Tell your doctor if you get any of these side effects:

- Hair loss
- Loose stools
- Feeling sick (nausea) or being sick (vomiting)
- Skin rash.

BLOOD TESTS:

Whilst you are taking these tablets it is essential that you attend for tests of your blood clotting. Your doctor will tell you how often you should attend for blood tests and they are necessary even if you have been prescribed the same dosage for a long time.

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 HPRA Pharmacovigilance Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Warfant tablets

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

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

Do not store above 25°C.

Store in the original packaging/container in order to protect from light and moisture.

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 Warfant Tablets contain

- The active substance is warfarin sodium. Each tablet contains warfarin sodium clathrate equivalent to 1mg, 3mg and 5mg of warfarin sodium.
- The other ingredients are lactose monohydrate, maize starch, sodium starch glycollate and magnesium stearate, alumina.

The 1mg tablets also contain Tartrazine Lake (E102), Amaranth Lake (E123), Indigo Carmine Lake (E132).

The 3mg tablets also contain Indigo Carmine Lake (E132).

The 5mg tablets also contain Erythrosine Lake (E127).

What Warfant Tablets look like and contents of the pack

1mg Tablets: Round brown uncoated tablet, scored and marked 'W1' on one side with company logo on reverse.

3mg Tablets: Round blue uncoated tablet, scored and marked 'W3' on one side with company logo on reverse.

5mg Tablets: Round pink uncoated tablet, scored and marked 'W5' on one side with company logo on reverse.

Pack size: The tablets are packaged in plastic pots (polypropylene containers) containing 100 or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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