

Package leaflet: Information for the patient

WARFARIN TEVA 0.5 mg, 1 mg, 2 mg, 2.5 mg, 3 mg, 5 mg, 6 mg, 7.5 mg and 10 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 further questions, please ask your doctor or your 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.

What is in this leaflet:

1. What **Warfarin Teva Tablets** are and what they are used for
2. What you need to know before you take **Warfarin Teva Tablets**
3. How to take **Warfarin Teva Tablets**
4. Possible side effects
5. How to store **Warfarin Teva Tablets**
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1. What Warfarin Teva Tablets are and what they are used for

Warfarin Teva Tablets contain an active substance called warfarin which belongs to a group of drugs called anticoagulants. They thin the blood and help prevent blood clots from forming in the heart and blood vessels.

You may be given Warfarin Teva Tablets to prevent or treat problems with blood clots in the veins. You may also be given Warfarin Teva Tablets to prevent problems with blood clots in the heart, if your heartbeat is irregular and your heart valves are damaged.

Warfarin Teva Tablets are not suitable for treating children.

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

Do not take Warfarin Teva Tablets

- if you are allergic to warfarin or to any of the other ingredients in the tablets (listed in section 6)
- if you are pregnant or you think that you may be pregnant
- if you have just had a baby (within the last two days)
- if you have had any bleeding problems including a stroke
- if you have had major surgery less than three days ago or if you are due to have an operation within the next three days
- when you are taking some medicines or other remedies (these are listed later in the leaflet)
- if your chance of having bleeding problems is higher than the possible benefit of treatment (discuss this with your doctor).

Warnings and precautions

Talk to your doctor or pharmacist before taking Warfarin Teva Tablets:

- if you are elderly
- if you have a bleeding disorder (any condition that causes you to bleed or to bruise easily)
- if you suffer with breathlessness or swollen ankles
- if you have very high blood pressure
- if you have recently had a stroke, or if you have a problem with the blood supply to the brain
- if you have an infection of the heart valve
- if you have a recent wound, or recent surgery
- if you have a problem with your liver or kidneys
- if you have thyroid problems
- if you have diarrhoea or vomiting, or a recent loss of or gain in your weight
- if you have fever or an acute illness
- if you have a malignant condition (cancer)
- if you have ever vomited blood, or passed blood in the stool
- if you have ever had a stomach ulcer
- if you have certain genetic conditions (your doctor will have talked to you about these)
- if you have vitamin K deficiency (lack of vitamin K)
- if you are taking some food supplements or if you are on a special diet.

Tell your doctor if you are due to have surgery, including dental surgery, as your dose of warfarin may need to be reduced or discontinued.

Other medicines and Warfarin Teva Tablets

It is very important that the warfarin levels in your blood remain steady within a certain range. Warfarin blood levels can be affected by other medicines which you may be taking and also by things you eat or drink. Some medicines can increase the effect of warfarin, and others may decrease the effect. This is why you must tell your doctor or pharmacist about any other drugs or remedies you are taking, including medicines you have obtained without a prescription.

You must not take Warfarin Teva Tablets if you are also taking other medicines which are used to prevent or treat blood clots. These are called 'fibrinolytic' drugs and include streptokinase, alteplase and similar drugs.

You must not take the herbal remedy St John's Wort during your treatment.

Check with your doctor first before taking these medicines:

- non-steroidal anti-inflammatory drugs (aspirin, diclofenac, celecoxib, numesulide, 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)
- sulfinpyrazone (for gout)
- glucosamine (for osteoarthritis)
- SSRI and SNRI anti-depressants.

You must also tell your doctor if you are taking any of the following medicines:

- drugs for a heart problem (amiodarone, quinidine, propafenone)
- drugs to lower blood cholesterol (clofibrate, cholestyramine, gemfibrozil, lovastatin, simvastatin)
- antibiotic drugs to treat bacterial infections (such as chloramphenicol, ciprofloxacin, co-trimoxazole, clarithromycin, erythromycin, metronidazole, rifampicin, sulfamethoxazole)
- drugs to treat fungal infections (fluconazole, griseofulvin, itraconazole, ketoconazole, miconazole)
- drugs to relieve pain (dextropropoxyphene, paracetamol, phenazone)

- drugs to treat stomach ulcers or acid problems (cimetidine, omeprazole, sucralfate)
- drugs for menstrual problems (danazol)
- drugs for diabetes (glibenclamide)
- drugs for gout (allopurinol)
- drugs for breast cancer (tamoxifen), prostate cancer (aminoglutethimide) or other cancers (capecitabine, erlotinib)
- drugs for sleeping problems (chloral hydrate, triclofos)
- the pill (oral contraceptives)
- anabolic steroids (stanozolol)
- drugs for alcoholism (disulfiram)
- drugs for thyroid deficiency (thyroxine)
- drugs for control of epilepsy (barbiturates, phenobarbitone, carbamazepine, phenytoin, primidone)
- drugs to suppress an immune response (azathioprine)
- methylphenidate (for attention deficit disorder)
- orlistat (for obesity)
- zafirlukast (for asthma)
- corticosteroids (for inflammation and many other diseases)
- nevirapine, ritonavir (used to treat HIV).

Warfarin Teva Tablets with food, drink and alcohol

Do not drink large amounts of alcohol while taking Warfarin Teva Tablets. Some foods and drinks, such as cranberry or grapefruit juice, liver, broccoli, sprouts and green leafy vegetables, can affect blood warfarin levels. Some food supplements may also affect warfarin levels. Discuss your diet with your doctor before making any changes.

Pregnancy, breast feeding and fertility

You must not take warfarin if you are pregnant. If you think you might be pregnant or planning to have a baby, or you are breast-feeding ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Warfarin Teva Tablets are not expected to have any effect on the ability to drive and use machines.

Warfarin Teva Tablets contain lactose and allura red

The product contains 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.

This product contains allura red AC (E129) which may cause allergic reactions (1 mg, 2 mg, 5 mg and 10 mg).

3. How to take Warfarin Teva Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The doctor will decide what dose you need. You will have regular blood tests to determine the right dose for you.

The recommended dose for adults is 10 mg daily for 2 days. If you are elderly, your doctor may decide to reduce the starting dose. After the second day, your dose of warfarin will depend on the results of your blood tests. Your doctor will arrange these tests at suitable intervals. After each blood test, you will be told how much warfarin to take each day. Take your tablets at the same time each day. Swallow the tablets whole with water.

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

If you take more Warfarin Teva Tablets than you should

If you take too many tablets, or if you have unexplained bleeding, tell your doctor or contact your nearest hospital immediately.

If you forget to take Warfarin Teva Tablets

If you forget to take a dose at the usual time, take it later the same day as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Warfarin Teva Tablets

Do not stop taking Warfarin Teva Tablets unless your doctor tells you to.

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 cause side effects, although not everyone gets them.

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

- unexplained bleeding, such as a nose bleed; blood in the urine or stools, or black stools
- an allergic reaction, such as breathlessness, itching and hives
- a painful red skin rash or skin blisters
- yellowing of the skin or the whites of the eyes.

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, tell your doctor as soon as possible:

- nausea, vomiting or diarrhoea
- a skin rash
- purple discoloration of the toes
- hair loss
- fever.

Adverse effects with no known frequency:

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on this leaflet.

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 HPR

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; e-mail: medsafety@hpra.ie

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

5. How to store Warfarin Teva Tablets

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label and carton {after abbreviation EXP}. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in original container in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Warfarin Teva Tablets contain

- The active substance is 0.5 mg, 1 mg, 2 mg, 2.5 mg, 3 mg, 5 mg, 6 mg, 7.5 mg or 10 mg warfarin sodium (as clathrate).
- The other ingredients are anhydrous lactose, pregelatinised starch, magnesium stearate, E104 (quinoline yellow) (1 mg, 2.5 mg, 6 mg and 7.5 mg), E129 (allura red AC) (1 mg, 2 mg, 5 mg and 10 mg), E132 (indigotine) (1 mg, 2 mg, 2.5 mg, 6 mg), E133 (brilliant blue FCF) (3 mg) and E172 (iron oxide black and red) (10 mg).

What Warfarin Teva Tablets look like and contents of the pack

Tablet shapes: Warfarin Teva 0.5 mg Tablets are flat and oblong. The other tablet strengths are capsule-shaped, scored tablets

Tablet markings: Warfarin Teva 0.5 mg Tablets are engraved "WARFARIN" on top of "TARO" on one side and "0.5" on the other side. The other strengths of Warfarin Teva Tablets are engraved with the tablet strength on one side and with "WARFARIN on top of TARO" on the other side.

Tablet colours: 0.5 mg white; 1 mg brown; 2 mg lavender; 2.5 mg green; 3 mg blue; 5 mg pink; 6 mg teal; 7.5 mg yellow; 10 mg dark red.

Packs contain 10, 20, 28, 30, 50, 56 or 100 tablets in blisters or 100 tablets in bottles. Not all sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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2132 JH Hoofddorp
The Netherlands

This leaflet was last revised in December 2021.