

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

Warfarin 5 Biotech, 5 mg, tablets

Warfarin sodium

Warfarin 5 Biotech contains sugar (sucrose: 8 mg per tablet and lactose: 139 mg per tablet).

Read all of this leaflet carefully before you start taking Warfarin 5 Biotech

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Warfarin 5 Biotech has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Warfarin 5 Biotech is and what it is used for
2. What you need to know before you take Warfarin 5 Biotech
3. How to take Warfarin 5 Biotech
4. Possible side effects
5. How to store Warfarin 5 Biotech
6. Contents of the pack and other information

1. What Warfarin 5 Biotech is and what it is used for

Warfarin 5 Biotech contains the active ingredient warfarin which belongs to a group of medicines called anticoagulants. It is used to decrease the clotting ability of the blood and therefore helps to prevent harmful clots from forming in the blood vessels.

Warfarin 5 Biotech is used to prevent and treat blood clots forming in the legs, lungs, brain or heart.

2. What you need to know before you take Warfarin 5 Biotech

Do not take Warfarin 5 Biotech

- if you are hypersensitive (allergic) to warfarin sodium or any of the other ingredients of Warfarin 5 Biotech listed in section 6.1
- if you recently had a stroke caused by bleeding in the brain
- if you have a bleeding situation
- if you have any bleeding disorder or disease
- if you had surgery within the last 72 hours or are going to have surgery in the next 72 hours
- if you have a peptic ulcer or other stomach disease that causes you to bleed internally
- if you have a severe wound
- if you have a prosthetic heart valve
- if you have an infection of the heart valves
- if your kidney or liver function is impaired
- if you have high blood pressure
- if you had an aneurysm (blood vein or artery that formed a sac or burst)
- if you have inflammation (swelling) of the pericardium, which is the fluid-filled sac that surrounds your heart (pericarditis)
- if you have an abnormal amount of fluid between the heart and pericardium (pericardial perfusion)
- if you had or are going to have surgery that involves your eyes, brain, back or nerves or any other major surgeries
- if you had a baby in the last 48 hours
- if you have severe arthritis (inflammation of the joints) affecting five or more joints at the same time
- if you have a Vitamin C deficiency
- if you have the possibility of losing your baby (threatened abortion)
- if you are younger than 18 years of age, because safety has not been established

- if you are taking other medicines that increase your risk of bleeding
- if you are taking other medicines to treat and prevent blocking of a blood vessel by a blood clot
- if you are pregnant or may become pregnant or breastfeeding, you baby.

Warnings and precautions

Take special care with Warfarin 5 Biotech

- if you have a genetic disorder called protein C deficiency making you prone to blood clots (thrombophilia);
- you should not stop your treatment with Warfarin 5 Biotech abruptly. Your doctor will decrease your dose gradually over three to four weeks;
- if you have a Vitamin K deficiency;
- medicines like Warfarin 5 Biotech, which work against vitamin K, might put you at risk for weaker bones (increased risk in fractures). You need extra attention to avoid this problem;
- if you suffer from dietary deficiency, are on antibiotic treatment, suffer from vascular disease, diabetes or have allergic disorders;
- if you had recent ischaemic stroke (caused by blockage of blood vessels in the brain);
- if you had an infection of the heart lining (bacterial endocarditis);
- if you previously had gastrointestinal bleeding;
- if you have a higher risk of bleeding for example if you are over 65 years of age or are unsteady on your feet and more likely to fall and injure yourself;
- very high blood pressure which is not controlled by medicines;
- problems with circulation of blood to the brain (cerebrovascular disease);
- if you have severe heart disease, liver or kidney problems;
- if you have anaemia (low haemoglobin causing extreme tiredness, breathlessness, poor resistance to infection);
- if you have a tumour or cancer;

- if you had trauma, had a recent wound or injury;
- if you use any anti-platelet medicines (such as clopidrogel, aspirin), because that can increase the risk of bleeding;
- if you have the condition calciphylaxis, where calcium builds up inside the blood vessels of the fat and skin;
- if you have an overactive thyroid gland;
- if you experience a painful and prolonged erection called priapism. This problem seems to be linked to a lack of protein C, and it often happens alongside another issue called warfarin-induced skin necrosis;
- if you experience a painful spot on the skin, which may look red or bleed at first. Later, it can form blisters and turn black from tissue death. People with lack of protein C levels seem to be at the highest risk;
- Be cautious if you have "wet" age-related eye disease that can blur your central vision and are taking Warfarin 5 Biotech because it could make you bleed inside your eye and lead to vision loss.

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.

Warfarin 5 Biotech may be affected by:

A number of things affect blood clotting and can therefore affect your Warfarin 5 Biotech treatment. It is important to follow the advice given below:

The following increases the effect of Warfarin 5 Biotech

- Weight loss
- Sudden illness such as the flu or feeling run down

- Stopping smoking, thus seek medical advice before you give up smoking
- Cranberry juice and cranberry products (and possibly grapefruit juice)
- Large amounts of alcohol

The following decreases the effect of Warfarin 5 Biotech

- Weight gain
- Stomach upset, diarrhoea
- Being sick (vomiting)

Keep your healthcare professionals 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.

Surgical operations:

Tell your doctor you are taking Warfarin 5 Biotech.

Due to the risk of bleeding, your doctor may need to lower your dose before an operation or removal of teeth. You should stop taking Warfarin 5 Biotech 3 to 5 days before and after surgery where there is a risk of severe bleeding. Make sure you tell your doctor or dentist you are taking Warfarin 5 Biotech. Depending on the reason you are using warfarin, Warfarin 5 Biotech may have to be replaced by another medicine (heparin).

Children and adolescents

Warfarin 5 Biotech should not be given to children 18 years and younger as the safety and effectiveness have not been established.

Other medicines and Warfarin 5 Biotech

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

Do not take Warfarin 5 Biotech and tell your doctor if you are taking:

- Fibrinolytic medicines to treat or prevent blood clots, such as alteplase, reteplase, tenecteplase, streptokinase and urokinase
- St John's wort (*Hypericum perforatum*) an herbal remedy for depression.

Check with your doctor first before taking these medicines:

- Clopidogrel (antiplatelet medicines to prevent or break down blood clots)
- non-steroidal-anti-inflammatory drugs (NSAIDs) for pain and inflammation including aspirin, ibuprofen, celecoxib, diclofenac, indomethacin, meloxicam
- sulfinpyrazone (for gout)
- Thrombin inhibitors (delaying blood clotting) such as bivalirudin, dabigatran
- dipyridamole (antiplatelet drugs to prevent or break down blood clots)
- heparin or medicines containing heparin, bivalirudin, fondaparinux, dabigatran, rivaroxaban, danaparoid, prostacyclin (other anticoagulants)
- Glycoprotein IIb/IIIa receptor antagonists such as eptifibatide, tirofiban and abciximab (antiplatelet drugs to prevent or break down blood clots)
- SSRI and SNRI anti-depressants such as citalopram, fluoxetine, paroxetine, venlafaxine
- glucosamine (for osteoarthritis)

Medicines which increase the effect of Warfarin 5 Biotech:

- prolonged, regular use of paracetamol (for pain or inflammation)
- antibiotics such as amoxicillin, levofloxacin and tetracycline

- allopurinol (for gout)
- capecitabine, erlotinib, tamoxifen (for types of cancer)
- disulfiram (for alcohol dependence)
- ketoconazole, fluconazole, itraconazole, miconazole (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)
- Vitamin K (in vitamin supplements or in cod liver oil).

Medicines which decrease the effect of Warfarin 5 Biotech:

- 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 (an increase in the amount of your vitamin K intake could reduce the effect of Warfarin 5 Biotech).

Medicines which have varying effects on Warfarin 5 Biotech:

- corticosteroids (for inflammation and many other diseases)
- nevirapine, ritonavir (for HIV infection).

Warfarin 5 Biotech with food, drink and alcohol

Patients should seek medical advice before undertaking any major changes in diet or using food supplements while taking Warfarin 5 Biotech.

Do not drink either cranberry juice or grapefruit juice or products containing it whilst taking Warfarin 5 Biotech.

Acute ingestion of a large amount of alcohol may inhibit the metabolism of Warfarin 5 Biotech and increase INR. Conversely, chronic heavy alcohol intake may induce the metabolism of Warfarin 5 Biotech.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving Warfarin 5 Biotech.

Do not take Warfarin 5 Biotech if you are pregnant, may become pregnant or have had a baby within the last 48 hours.

Woman of child-bearing age who are taking Warfarin 5 Biotech should use contraception medicine during their treatment with Warfarin 5 Biotech and for at least 1 month after the final dose of Warfarin 5 Biotech.

Do not breastfeed your infant while taking Warfarin 5 Biotech.

Driving and using machines

It is not always possible to predict to what extent Warfarin 5 Biotech may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Warfarin 5 Biotech affects them.

Warfarin 5 Biotech 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 5 Biotech contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Warfarin 5 Biotech

Do not share medicines prescribed for you with any other person.

Always take Warfarin 5 Biotech exactly as your doctor, or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Never take more or less tablets than your recommended dose.

Your doctor or health care provider should check your progress with Warfarin 5 Biotech at regular visits.

A blood test must be taken regularly to see how fast your blood is clotting. This test is called INR (international normalised ratio) test.

Adults:

The usual starting dose of Warfarin 5 Biotech is 5 mg once a day. Then, your dose may be adjusted, depending on your condition and results of your blood tests.

Try to take the Warfarin 5 Biotech at the same time each day.

Your doctor will tell you how long your treatment with Warfarin 5 Biotech will last. Do not stop treatment

early. If you have the impression that the effect of Warfarin 5 Biotech is too strong or too weak, tell your doctor or pharmacist.

If you take more Warfarin 5 Biotech than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of taking too much Warfarin 5 Biotech include bleeding, black tarry stools, blood in urine, heavy bleeding or oozing from cuts and wounds or unusually heavy menstrual bleeding.

Activated charcoal should be used if you have symptoms 1 hour after taking too much (50 g for adults and 1g/kg for children) Warfarin 5 Biotech.

If you forget to take Warfarin 5 Biotech

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

4. Possible side effects

Warfarin 5 Biotech can have side effects.

Not all side effects reported for Warfarin 5 Biotech are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Warfarin 5 Biotech, please consult your health care provider for advice.

If any of the following happens, stop taking Warfarin 5 Biotech and tell your doctor immediately or go the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,

- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Warfarin 5 Biotech. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- an artery in the brain bursting and causing bleeding in the brain (cerebral haemorrhage)
- bleeding that occurs within the skull of head but outside the actual brain tissue (cerebral subdural haematoma)
- escape of blood from a ruptured blood vessel (haemorrhage)
- haemothorax (blood collects between your chest wall and your lungs)
- bleeding in the gastrointestinal tract, from the mouth to the rectum. When there is a lot of blood loss over a short time, symptoms may include vomiting red blood, vomiting black blood, bloody stool, or black stool (Gastrointestinal haemorrhage, rectal haemorrhage, haematemesis).
- severe pain in the upper abdomen (a sign of inflammation of the pancreas) (pancreatitis)
- the production of dark sticky faeces containing partly digested blood, as a result of internal bleeding or the swallowing of blood (melaena).
- damage to your liver that results in dark urine (hepatic dysfunction)
- 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 you have a bone disease that occurs when the body loses too much bone, makes too little bone, or both. As a result, bones become weak and may break from a fall or, in serious cases, from sneezing or minor bump (osteoporosis)
- if you have blood in your urine (haematuria)
- drop in number of red blood cells, blood haemoglobin (shown in blood tests).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- lower-than-normal number of leukocytes (white blood cells) in the blood
- too many granulocytes (certain type of white blood cells) in the blood
- reduced blood clotting (by inhibiting vitamin K synthesis), may also increase the risk of bleeding
- diarrhoea
- nausea
- vomiting
- feeling bloated
- loss of appetite
- stomach pain
- kidney damage (leading to swelling in different parts of the body, abnormal amount of protein in the urine or difficulty passing urine).

Side effects with unknown frequency

- fever
- low number of red blood cells (anaemia)
- bleeding from the nose (epistaxis)
- yellowing of the skin and white of eyes (jaundice)
- skin rash
- hair loss
- a rash of purple spots on the skin caused by internal bleeding from small blood vessels (purpura)
- painful skin lesion seen in patients with moderate to severe kidney problems

- skin redness
- skin necrosis (also called warfarin-induced skin necrosis-condition in which skin and tissue death occurs)
- arm or leg become severely damaged and may die to problems with the veins in that limb
- sores or white spots in your mouth or throat.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Warfarin 5 Biotech.

5. How to store Warfarin 5 Biotech

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Warfarin 5 Biotech contains

The active substance is 5 mg warfarin sodium

The other ingredients are lactose monohydrate, sucrose, maize starch, purified water, pregelatinized starch, magnesium stearate and erythrosine aluminium lake (E127).

What Warfarin 5 Biotech looks like and contents of the pack

Pink coloured, circular, flat faced bevelled edged uncoated tablets with breakline on one side and plain on the other side.

Warfarin 5 Biotech are packed in Opaque blisters. Each blister contains 14 tablets, which are placed in an outer carton containing 2 blisters.

Holder of Certificate of Registration

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