

Package leaflet: Information for the user

Marevan® 0.5mg 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.

What is in this leaflet

1. What Marevan 0.5mg Tablets are and what they are used for
2. What you need to know before you take Marevan 0.5mg Tablets
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1. What Marevan 0.5mg Tablets are and what they are used for

Marevan 0.5mg Tablets contain warfarin sodium. 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 is used to prevent and treat blood clots forming in the legs, lungs, brain and heart.

2. What you need to know before you take Marevan 0.5mg Tablets

Do not take Marevan 0.5mg Tablets if you:

- are allergic to warfarin sodium or 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 Marevan 0.5mg 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, pharmacist or nurse before taking Marevan 0.5mg 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
 - 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
 - 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 if 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 Marevan, 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. Blood tests will be more frequent if you have had your dose of Marevan changed, if you have started or stopped taking other medicines, or have liver or kidney problems.

Things which affect Marevan:

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

| Increases effect of Marevan | Reduces effect of Marevan | 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 | Vitamin K supplements should be taken only if prescribed by doctors as sudden increase in Vitamin K intake may decrease the effect of Warfarin. |
| | Foods such as liver, broccoli, brussel sprouts and green leafy vegetables contain large | Don't make any major changes to your diet whilst taking Marevan. |

| | | |
|--|---|--|
| Cranberry juice and cranberry products (and possibly grapefruit juice) | amounts of vitamin K. | Don't drink either cranberry juice or grapefruit juice or products containing these whilst taking Marevan. |
| Large amounts of Alcohol | | Only drink small amounts whilst taking Marevan. |
| 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 go to that you are taking Marevan (Warfarin). You should also have received a booklet which includes more information about Marevan (warfarin) 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 before an operation or removal of teeth. You should stop taking Marevan (warfarin) 72 hours before and after surgery where there is a risk of severe bleeding. Make sure you tell your doctor or dentist you are taking Marevan.

Other medicines and Marevan 0.5mg Tablets

Many medicines affect the way Marevan works. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including over the counter medicines, herbal remedies and vitamin supplements.

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

- alteplase, reteplase, streptokinase, tenecteplase, urokinase (fibrinolytic drugs 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 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 such as citalopram, fluoxetine, paroxetine, venlafaxine.
- 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.

Medicines which increase the effect of Marevan: 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 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).

Medicines which decrease the effect of Marevan. 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 (an increase in the amount of your vitamin K intake could reduce the effect of warfarin).

Medicines which have varying effects on Marevan: Tell your doctor or pharmacist if you are taking:

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

Marevan 0.5mg Tablets with food, drink and alcohol

Patients should seek medical advice before undertaking any major changes in diet while taking Marevan 0.5mg Tablets. Patients should be advised to avoid cranberry products. Acute ingestion

of a large amount of alcohol may inhibit the metabolism of warfarin and increase INR. Conversely, chronic heavy alcohol intake may induce the metabolism of warfarin.

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.

Marevan is unlikely to harm your baby during breastfeeding, if taken at the correct dose.

Driving and using machines

Marevan has no known effect on the ability to drive or operate machines.

Marevan 0.5mg Tablets 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.

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 Marevan 0.5mg Tablets

Always take this medicine exactly as your doctor or pharmacist 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.

Once you have been stabilised on this medicine the usual dose is between 3 - 9 mg. Try to take the medicine at the same time each day. The score line is not intended for breaking the tablet.

If you take more Marevan 0.5mg 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 much Marevan 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 Marevan 0.5mg Tablets

If you usually take your Marevan Tablets in the evening and you have forgotten to take it, 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 Marevan Tablets in the morning and have forgotten to take it 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 as normal.
- if it is more than two hours late, take the dose as soon as you remember and then continue as normal.

However, if it is time to take your next dose leave out the missed dose Do not take a double dose to make up for a forgotten dose.

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 GP or anticoagulant clinic for advice.

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.

Do not be concerned about this list of side effects. You may not get any of them, but it is important to know what to do if they occur.

Stop taking Marevan 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.
- 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.

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

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

- 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 a sign of a bleed in the brain.
- painful, blue-purple coloured toes
- yellowing of the skin and white of eyes (jaundice), problems with your liver
- severe pain in the upper abdomen (a sign of inflammation of the pancreas)
- difficulty in breathing and chest pain due to collection of blood in the chest
- 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)

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 Website: 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 Marevan 0.5mg Tablets

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

Store in original package/container in order to protect from light.

Do not store above 25°C.

Do not use this medicine after the expiry date printed on the container. The expiry date refers to the last day of that month.

Return any unused tablets to your pharmacist who can dispose of them safely for you.

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 Marevan 0.5mg Tablets contain

- The active substance is Warfarin. Each tablet contains 0.5mg of warfarin.
- The other ingredients are lactose, maize starch, pregelatinized maize starch, purified water, sodium starch glycolate and magnesium stearate.

What Marevan 0.5mg Tablets look like and contents of pack

The 0.5mg tablet is white, flat, circular, bevel-edged uncoated tablets having “M” breakline “0.5” on one side and plain on the other side.

The tablets are packaged in either plastic pots (polypropylene containers) containing 28, 56, 100, 112 or 500 tablets, or in aluminium foil blister packs of 28, 56, or 112 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder

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