



MercuryPharma

Package leaflet: Information for the user Marevan® 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 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 Tablets are and what they are used for
2. What you need to know before you take Marevan Tablets
3. How to take Marevan Tablets
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT MAREVAN TABLETS ARE AND WHAT THEY ARE USED FOR

Marevan contains warfarin. 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 or heart. The tablets come in three strengths and colours: 1mg (brown); 3mg (blue) 5mg (pink).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MAREVAN TABLETS

Do not take Marevan Tablets if you:

- are **allergic** to Warfarin or to 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** ①
- 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 inflammatory drugs (**NSAIDs**), **aspirin** or **anti-clotting medicines** as this may increase the risk of bleeding. (See Section 2 'Other medicines and Marevan 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 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
- have 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 warfarin, 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 warfarin 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 warfarin treatment. To make sure your warfarin works properly and safely, it is important to follow the advice below.

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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 amounts of vitamin K.	Don't make any major changes to your diet whilst taking warfarin.
Cranberry juice and cranberry products (and possibly grapefruit juice)		Don't drink either cranberry juice or grapefruit juice or products containing these whilst taking warfarin.
Large amounts of alcohol		Only drink small amounts whilst taking warfarin.
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 ③

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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 warfarin.

Other medicines and Marevan Tablets

Many medicines affect the way warfarin 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 Warfarin 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, dipyridamol, eptifibatide, tirofiban (antiplatelet drugs to prevent or break down blood clots)
- heparin or medicines containing heparin, bivalirudin, fondaparinux, dabigatran, rivaroxaban, danaparoid, prostacyclin (other anticoagulants)
- sulfapyrazone (for gout)
- glucosamine (for osteoarthritis)
- SSRI and SNRI anti depressants such as citalopram, fluoxetine, paroxetine, venlafaxine.

Medicines which increase the effect of Warfarin: Tell your doctor if you are taking:

- prolonged, regular use of paracetamol (for pain or inflammation)
- antibiotics such as amoxicillin, levofloxacin and tetracycline
- vitamin K (in vitamin supplements or in cod liver oil): Lowering your Vitamin K intake suddenly could increase the effect of Warfarin
- 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) ④

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- 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 Warfarin. 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).

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

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

Marevan Tablets with food, drink and alcohol:

Patients should seek medical advice before undertaking any major changes in diet while taking warfarin 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.

Important Information about some of the ingredients of Marevan Tablets:

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.

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3. HOW TO TAKE MAREVAN 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.

If you take more Marevan 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 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 Warfarin 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. Never take a double dose to catch up.

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.

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.

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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)
- severe pain in the upper abdomen (a sign of inflammation of the pancreas)
- 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.

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 at: 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 MAREVAN TABLETS

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

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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 Tablets contain:

The active substance is Warfarin. Each tablet contains 1mg, 3mg or 5mg of warfarin.

The other ingredients are lactose, maize starch, pregelatinized maize starch, purified water, sodium starch glycolate and magnesium stearate.

The 1mg tablets also contain dispersed blue 17488 Ansteads, Yellow Iron oxide (E172), Red Iron oxide (E172).

The 3mg tablets also contain dispersed blue 17488 Ansteads.

The 5mg tablets also contain dispersed pink 11150 Ansteads.

What Marevan Tablets looks like and contents of pack:

The 1mg tablet is brown coloured, flat, circular, bevel-edged uncoated tablets having "M" breakline "1" on one side and plain on the other side.

The 3mg tablet is blue coloured, flat, circular, bevel-edged uncoated tablets having "M" breakline "3" on one side and plain on the other side.

The 5mg tablet is pink coloured, flat, circular, bevel-edged uncoated tablets having "M" breakline "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:

Mercury Pharma Group Ltd,
Capital House, 85 King William Street, London EC4N 7BL, UK

Manufacturer:

Bristol Laboratories Ltd., Laporte Way, Luton, Bedfordshire, LU4 8WL, UK

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