

MAREVAN*

Warfarin sodium

1 mg, 3 mg, 5 mg tablets

What is in this leaflet

Please read this leaflet carefully before you start taking MAREVAN.

This leaflet answers some common questions about MAREVAN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MAREVAN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What MAREVAN is used for

MAREVAN contains the active ingredient warfarin sodium. It is a synthetic, anticoagulant agent which belongs to the coumarin family of anticoagulants. Some people refer to anticoagulants as "blood thinners".

Anticoagulants decrease the clotting ability of the blood and help prevent a harmful clot (thrombus) from forming in the blood vessels. Anticoagulants are used as treatment for certain blood vessel, heart and lung conditions.

MAREVAN is used for the treatment and management of conditions whereby the formation of blood clots has prevented free-flow of blood, especially in the veins.

Blood clots in the body can reduce the amount of oxygen and nutrients delivered to body tissues and organs as well as affect the removal of waste from tissues and organs. This affects body functions.

MAREVAN interferes with the function of certain factors, which are responsible for blood clotting.

These factors require a vitamin called Vitamin K in order to function. The amount of Vitamin K in your body influences how well your blood clots.

Your doctor or pharmacist may advise you on your diet as some foods such as large amounts of leafy green vegetables, dairy products fortified with vitamin K, fats and oils, contain vitamin K.

MAREVAN tablets are used in conditions such as:

- coronary occlusions (blockage in blood vessels of the heart)
- deep vein thrombosis (clots in veins)
- pulmonary embolism (blocking of blood vessels in the lungs)
- peripheral vascular thromboembolic states (blockage of blood vessels in different parts of the body)

Your doctor may have prescribed MAREVAN for another reason.

Ask your doctor if you have any questions about why MAREVAN has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take MAREVAN

When you must not take it

Do not take MAREVAN if you have an allergy to:

- warfarin, similar medicines, or any of the ingredients listed at the end of this leaflet

Always check the ingredients to make sure you can take this medicine.

Some of the symptoms of an allergic reaction may include:

- difficulty breathing and swallowing
- shortness of breath
- swelling of the face, tongue, lips, mouth, throat or other parts of the body
- fever
- hives on the skin, rash, or itching.
- low blood pressure

Do not take MAREVAN if:

- you suffer from:
 - bleeding in the brain (haemorrhagic stroke)
 - bleeding tendencies
- you are:
 - within 72 hours of major surgery with risk of severe bleeding
 - during the first 48 hours after giving birth
 - taking medicines that dissolve blood clots such as streptokinase or altepase (these are known as fibrinolytic or thrombolytic medicines)
 - about to undergo dental surgery

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking MAREVAN, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. you have allergies to:

- Any other medicines including warfarin
- Any other substances, such as foods, preservatives or dyes.

2. you have, or have had, the following medical conditions:

- a deficiency in Protein C
- bleeding tendencies
- heart problems
- liver or kidney disease
- severe high blood pressure
- intestinal disease (such as coeliac disease)
- a stroke caused by a blood clot (ischaemic stroke)
- an ulcer in your stomach or duodenum (peptic ulcer)
- problems with your thyroid
- long lasting illness
- weight loss or gain
- diarrhoea and/or vomiting
- warfarin resistance
- genetic variability
- lactose or galactose intolerance

3. you are pregnant or intend to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

4. you are breastfeeding or planning to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

5. have given up smoking.

Your doctor may need to reduce your dosage.

If you have not told your doctor about any of the above, tell them before you start taking MAREVAN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking MAREVAN.

MAREVAN interacts with other medications, herbal remedies (St John's Wort), vitamins, alcohol and many foods and food supplements (cranberry juice).

Some medicines may interfere with MAREVAN and affect how it works. These include:

- aspirin
- medications called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen
- medicines that treat:
 - blood clots or which affect the clotting of your blood
 - heart/cardiovascular disease e.g. angina or after you've had a heart attack
 - gout
 - depression

These medicines may be affected by MAREVAN or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines, vitamins or supplements to be careful with or avoid while taking MAREVAN.

How to take MAREVAN

How much to take

Take MAREVAN as directed by your doctor or pharmacist. Never change the dose yourself.

Your doctor and pharmacist will be able to tell you:

- how many tablets to take at each dose
- how many doses to take each day

- when to take each of your doses

The label on the pack that the tablets were supplied in will give the same information. If there is something that you do not understand, ask either your doctor or pharmacist.

The usual starting dose of MAREVAN is 10 mg to 15 mg daily, depending on your age and weight.

Elderly people may require smaller doses as they are more sensitive to the effects of MAREVAN.

Your doctor will do some blood tests in order to check how well your blood is clotting in order to determine how much MAREVAN you need to take.

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

If you take the wrong dose, MAREVAN may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

MAREVAN should be taken regularly at the same time each day. If you have just missed your scheduled dose, take it as soon as you remember and continue as before.

If you have forgotten to take one dose of MAREVAN and it is almost time to take your next scheduled dose, then skip the dose you have missed, and continue taking MAREVAN as directed by your doctor or pharmacist.

If you have forgotten to take more than one dose, contact your doctor or pharmacist for advice.

Do not take a double dose to make up for the dose you missed. This may increase the chance of unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking MAREVAN

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking MAREVAN.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

See your doctor if you feel that your condition is not improving or getting worse. Your doctor may do some tests from time to time to make sure the

medicine is working and to prevent unwanted side effects.

Take extra care when participating in physical activities such as sport while taking this medicine, as even minor injury may result in bleeding/bruising.

Eat a normal, balanced diet. This minimises the possibility of food interfering with MAREVAN. Your doctor or pharmacist may advise you on your diet.

Remind any doctor, dentist or pharmacist you visit that you are taking MAREVAN.

Things you must not do

Do not stop taking this medicine suddenly or lower the dosage without checking with your doctor. Your doctor will advise you when to stop taking MAREVAN.

Do not take MAREVAN to treat any other complaints, unless your doctor tells you to.

Do not give MAREVAN to anyone else, even if they have the same condition as you.

Things to be careful of

Driving or using machines

Be careful driving or operating machinery until you know how MAREVAN affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or

anyone else may have taken too much MAREVAN.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MAREVAN.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

General disorders:

- fever
- nose bleeds

Nervous system disorders:

- headache
- seizures

Cardiovascular disorders:

- chest pain, rapid heart rate and shortness of breath

Gastrointestinal disorders:

- diarrhoea
- stomach cramps
- nausea and vomiting

Metabolism and nutrition disorders:

- hair loss

Skin and subcutaneous tissue disorders:

- skin rash
- yellowish pigmentation of the skin
- inflammation of small blood vessels mainly

affecting the skin (a condition known as leukocytoclastic vasculitis)

Renal and urinary disorders:

- kidney disease (nephropathy)

Respiratory disorders:

- calcium deposits in windpipe (trachea) and air passages of the lungs (bronchi) (a condition known as tracheobronchial calcification). This is a very rare side effect which may affect up to 1 in 10,000 people.

Tell your doctor immediately if you notice any of the following symptoms:

Bleeding related events:

- unexplained nose bleeds or bleeding gums
- unusual bleeding or bruising under the skin
- heavy bleeding or oozing from cuts and wounds
- black bowel motions
- pink, dark red or brown urine
- vomiting blood
- in women, unusually heavy period of 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 signs of a bleed in the brain
- painful, blue-purple coloured toes

Skin and subcutaneous tissue disorders:

- a painful skin rash. This occurs more frequently in patients with chronic kidney disease

If any of the following happen, stop taking MAREVAN and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- fever
- low blood pressure
- severe skin rash, itching or hives

These are very serious side effects. If you have them, you may have had a serious allergic reaction

to MAREVAN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

MAREVAN interacts with many other medicines. This can affect your blood clotting which means that you could experience an increase in bleeding time or increased risk of clotting. Tell your doctor if you have any signs of unusual bleeding, as this may mean that your body is getting more medicine than it needs.

After taking MAREVAN

Storage

Keep your tablets in the original packaging. Replace the cap after use.

Keep your tablets in a cool dry place, away from moisture, heat or sunlight where the temperature stays at or below 25°C.

Do not store MAREVAN in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat, dampness and light can destroy some medicines.

Follow the instructions on the bottle on how to take care of your medicine properly.

Keep it where children cannot reach it. A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Do not take this medicine after the expiry date.

Product description

What it looks like

MAREVAN 1 mg tablets are brown uncoated round flat bevelled edge tablets, engraved DF/M1 on one side.

MAREVAN 3 mg tablets are pale blue uncoated round flat bevelled edge tablets, engraved DF/M3 on one side.

MAREVAN 5 mg tablets are pink uncoated round flat bevelled edge tablets, engraved DF/M5 on one side.

Ingredients

Active ingredient(s):

- warfarin sodium

Inactive ingredients:

The 1 mg, 3 mg and 5 mg tablets contain the following excipients:

- lactose monohydrate
- magnesium stearate
- maize starch
- pregelatinized maize starch
- sodium starch glycolate

The 1 mg tablets also contain the colourants:

- indigo carmine
- iron oxide red
- iron oxide yellow

The 3 mg tablets also contain the colourant:

- indigo carmine

The 5 mg tablets also contain the colourant:

- erythrosine

Potential allergens – lactose monohydrate

Sponsor details

Marevan is supplied in New Zealand by:
Douglas Pharmaceuticals Ltd
P O Box 45 027
Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

This leaflet was prepared on 10 February 2026

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