MAREVAN™ Tablets

Warfarin Tablets 1 mg, 3 mg and 5 mg

New Zealand Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using 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 Tablets are used for

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 contains an active ingredient called warfarin. 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 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 this medicine 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 any:

- Medicine containing warfarin
- Of the ingredients listed at the end of this leaflet.
- Other similar medicines.

Some of the symptoms of an allergic reaction may include:

- Severe skin rash, itching or hives
- Swelling of the face, lips, mouth or throat
- Difficulty breathing and swallowing
- Fever
- Low blood pressure

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy. If you are considering becoming pregnant while taking this medicine, talk to your doctor who can discuss the risks and benefits with you.

Do not take this medicine if you suffer from:

- Bleeding in the brain (haemorrhagic stroke)
- Bleeding tendencies

Do not take MAREVAN if 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 after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medically confirmed 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

Tell your doctor if you are breast-feeding.

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

Tell your doctor if you 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 him/her before you start taking MAREVAN.

Taking other medicines

MAREVAN interacts with other medications, herbal remedies (St John's Wort), vitamins, alcohol, and many foods and food supplements (cranberry juice). You must tell your doctor or pharmacist if you are taking any other medication including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:

- Aspirin
- Medications called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen
- Medications 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

There are various other medications which may interact with MAREVAN your doctor or pharmacist will have a complete list of the medicines that may cause problems when taken with MAREVAN.

How to take MAREVAN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

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 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.

If you have any questions about the dose that you have been prescribed you should ask your doctor or pharmacist.

How to take MAREVAN

MAREVAN tablets may be swallowed 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

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 your 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 that you have missed.

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 may have taken too much, or if anyone else has taken any MAREVAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using MAREVAN Tablets

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

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

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

See your doctor if you feel that you 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.

Things you must not do

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

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Your doctor will advise you when to stop taking MAREVAN.

If you are unsure whether you should stop taking MAREVAN talk to your doctor or pharmacist.

Things to be careful of

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

Things that would be helpful

Eat a normal, balanced diet.

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

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 some side effects. Sometimes they are serious, most of the time they are not. Your doctor or pharmacist will be able to answer any questions you may have.

If you think you are having an allergic (hypersensitivity) reaction to MAREVAN, TELL YOUR DOCTOR IMMEDIATELY.
Symptoms include:

- Severe skin rash, itching or hives
- Swelling of the face, lips, mouth or throat
- Difficulty breathing and swallowing
- Fever
- Low blood pressure

Other side effects reported with MAREVAN are:

- Headache
- Seizures
- Chest pain, rapid heart rate and shortness of breath
- Skin rash
- Hair loss
- Diarrhoea
- "Purple" coloured toes or you feel a pain in the toes.
- Bruising or purplish areas on the skin
- Yellowish pigmentation of the skin
- Black bowel motions
- Fever
- Nausea and vomiting
- Vomiting blood
- Nose bleeds
- Stomach cramps
- Blood in the urine
- A painful skin rash. This occurs more frequently in patients with chronic kidney disease.

• Kidney disease (nephropathy)

Tell your doctor if you experience any of these symptoms.

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.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After using MAREVAN

Storage

Keep your tablets in the bottle until it is time to take them. Replace cap after use.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store MAREVAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat, dampness and light can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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

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

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

Ingredients

MAREVAN tablets contain 1 mg, 3 mg or 5 mg of warfarin sodium as the active ingredient.

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

- Lactose monohydrate
- Magnesium stearate
- Maize starch
- · Pregelatinised 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

MAREVAN tablets contain lactose.

Supplier

MAREVAN tablets are supplied by:

GlaxoSmithKline NZ Limited

Private Bag 106600

Downtown Auckland

New Zealand

Trade marks are owned by or licensed to the GSK group of companies.

© 2023 GSK group of companies or its licensor.

This leaflet was prepared on 14 March 2023.

Version 7.0