MAREVAN

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking MAREVAN?

MAREVAN contains the active ingredient warfarin sodium. 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.

For more information, see Section 1. Why am I taking MAREVAN? in the full CMI.

2. What should I know before I take MAREVAN?

Do not use if you have ever had an allergic reaction to MAREVAN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take MAREVAN? in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take MAREVAN?

- The usual starting dose of MAREVAN is 10 to 15 mg daily, depending on your age and weight
- Take MAREVAN as directed by your doctor or pharmacist. Never change the dose yourself

More instructions can be found in Section 4. How do I take MAREVAN? in the full CMI.

5. What should I know while taking MAREVAN?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using MAREVAN Tell your doctor if you become pregnant while taking this medicine See your doctor if you feel that your condition is not improving or getting worse 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
Things you should not do	 Do not stop using 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 your medicine to anyone else, even if they have the same condition as you
Looking after your medicine	 Store below 25°C Store in original packaging

For more information, see Section <u>5. What should I know while taking MAREVAN?</u> in the full CMI.

6. Are there any side effects?

Side effects which have been reported include fever, nose bleeds, headache, seizures, chest pain, rapid heart rate and shortness of breath, diarrhoea, black bowel motions, stomach cramps, vomiting blood, nausea and vomiting, hair loss, skin rash, "purple" coloured toes or you feel a pain in the toes, bruising or purplish areas on the skin, yellowish pigmentation of the skin, a painful skin rash, blood in the urine and kidney disease (nephropathy). Serious side effects includes having allergic reactions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

MAREVAN

Active ingredient(s): warfarin sodium 1mg, 3mg, 5mg

Consumer Medicine Information (CMI)

This leaflet provides important information about using MAREVAN. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MAREVAN.

Where to find information in this leaflet:

- 1. Why am I taking MAREVAN?
- 2. What should I know before I take MAREVAN?
- 3. What if I am taking other medicines?
- 4. How do I take MAREVAN?
- 5. What should I know while taking MAREVAN?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

1. Why am I taking MAREVAN?

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 vessels, 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)

2. What should I know before I take MAREVAN?

Warnings

Do not take MAREVAN if:

- you are allergic to warfarin, or other similar medicines, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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
 - feve
 - low blood pressure
- 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

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have any other medical conditions including:
 - 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
 - take any medicines for any other condition
- have given up smoking. Your doctor may need to reduce your dosage

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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.

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

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist 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.

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. 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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MAREVAN.

4. How do I 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 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

How to take it

MAREVAN tablets may be swallowed whole with a glass of water

When to take MAREVAN

- 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
- continue taking your medicine for as long as your doctor tells you

If you forget to use MAREVAN

MAREVAN should be used 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 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 you missed.

If you use too much MAREVAN

If you think that you have used too much MAREVAN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 0800 POISON or 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking MAREVAN?

Things you should do

If you are about to start on any new medicine, remind 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.

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.

Call your doctor straight away if you:

• become pregnant while taking this medicine

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

Things you should not do

- do not stop using 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 your medicine to anyone else, even if they have the same condition as you

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MAREVAN affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- store below 25°C
- store in original packaging. Replace cap after use.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills

Heat, dampness and light can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less	serious side effects	What to do		
Gen	eral disorders:	Speak to your		
•	fever nose bleeds	doctor if you have any of these less		
Nerv	vous system disorders:	serious side		
•	headache seizures	effects and they worry you.		
Card	liovascular disorders:			
•	chest pain, rapid heart rate and shortness of breath			
Gast	trointestinal disorders:			
•	diarrhoea black bowel motions stomach cramps vomiting blood nausea and vomiting			
Metabolism and nutrition disorders:				
•	hair loss			
Skin and subcutaneous tissue disorders:				
•	skin rash "purple" coloured toes or you feel a pain in the toes bruising or purplish areas on the skin			
	yellowish pigmentation of the skin a painful skin rash. This occurs			
	more frequently in patients with chronic kidney disease			
Ren	Renal and urinary disorders:			
•	blood in the urine kidney disease (nephropathy)			

Serious side effects

Serious side effects	What to do
 Immune system disorders and allergic reactions: severe skin rash, itching or hives swelling of the face, lips, mouth or throat difficulty breathing and swallowing fever low blood pressure 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via https://pophealth.my.site.com/carmreportnz/s/

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MAREVAN contains

A ativa in avadiant	aufauia aadia	
Active ingredient	warfarin sodium	
(main ingredient)		
Other ingredients	The 1 mg, 3 mg and 5 mg	
(inactive ingredients)	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 carmineiron oxide rediron 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	

Do not take this medicine if you are allergic to any of these ingredients.

What MAREVAN looks like

MAREVAN 1 mg tablets are brown uncoated round flat bevelled edge tablets, engraved DF/M1 on one side. (TT50-1218)

MAREVAN 3 mg tablets are pale blue uncoated round flat bevelled edge tablets, engraved DF/M3 on one side. (TT50-1218a)

MAREVAN 5 mg tablets are pink uncoated round flat bevelled edge tablets, engraved DF/M5 on one side. (TT50-1218b)

Who distributes MAREVAN

GlaxoSmithKline NZ Ltd Private Bag 106600 Downtown Auckland 1143 New Zealand

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