

NEW ZEALAND CONSUMER MEDICINE INFORMATION

COUMADIN

Warfarin sodium tablets 1mg, 2 mg and 5 mg.



What is in this leaflet

Please read this leaflet carefully before you start taking COUMADIN.

This leaflet answers some common questions about COUMADIN.

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 COUMADIN 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 COUMADIN is used for

COUMADIN contains an active ingredient called "warfarin". It helps to prevent blood from excessive clotting or forming harmful clots.

This medicine belongs to a group of medicines called anticoagulants. Some people refer to anticoagulants as 'blood thinners'. Excessive clotting sometimes occurs when physical mobility is low. If excessive clotting is not treated, it can lead to serious health problems such as strokes or heart attacks.

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

Your doctor may have prescribed COUMADIN for another reason.

There are two brands of warfarin in New Zealand. They are called COUMADIN and MAREVAN.

Do not change from one brand to the other. You should not combine these brands.

There is no evidence that COUMADIN is addictive.

COUMADIN is available only with a doctor's prescription.

Before you use COUMADIN

When you must not take it

Do not take COUMADIN during pregnancy

Taking COUMADIN during pregnancy may harm the developing baby. If you are considering becoming pregnant while taking COUMADIN, tell your doctor who can help you weigh the benefits of taking COUMADIN against the possible risks.

Do not take COUMADIN if you have an allergy to:

- warfarin
- any of the ingredients in COUMADIN listed at the end of this leaflet.
- MAREVAN (another brand of warfarin)

Some of the symptoms of an allergic reaction may include itchy skin rash, difficulty breathing; swelling of the face and tongue.

Do not take COUMADIN if you have a history of bleeding tendencies or abnormal blood cells.

COUMADIN may make bleeding tendencies worse

Do not take COUMADIN if you have moderate to severe high blood pressure. The risk of bleeding in this situation may be increased by taking COUMADIN.

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.

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

Before you start to use it

You must tell your doctor if you:

- Are breastfeeding
- Are going to have any dental treatment
- Have recently had or are going to undergo any surgical procedures or operations.
- Are starting any sports activities that may result in traumatic injury
- Are going to travel or go on holidays

Your doctor or pharmacist is best able to advise you about combining these situations with taking COUMADIN.

Tell your doctor if you currently have or have had any of the following health or medical conditions:

- Liver, kidney or intestinal disease such as coeliac disease
- High blood pressure
- A deficiency in Protein C
- An ulcer in your stomach or duodenum
- Red or black bowel motions
- Internal bleeding such as bleeding in the brain
- Bleeding tendencies

- Fits or convulsions
- Thyroid problems
- Heart problems
- Psychiatric problems
- Severe diabetes
- Infections, diarrhoea, vomiting or fever
- Alcoholism
- Severe allergies
- Warfarin resistance
- Sudden changes in weight
- Have recently stopped smoking

Your doctor will need to consider all these factors when advising you about taking COUMADIN.

Tell your doctor or pharmacist if you are taking any other medications, including those you buy might from a chemist, supermarket or health food shop.

Some commonly used medicines and products that may interfere with COUMADIN include:

- Aspirin
- Any medication used to treat arthritis (including glucosamine and chondroitin)
- Anti-inflammatories (NSAIDs such as naproxen, fenopron, indomethacin, ibuprofen, sulindac)
- Some medications used to treat blood clots, heart attacks or angina
- Antidepressants
- Antihistamines
- Some antibiotics
- Vitamin C
- Vitamin K
- St John's Wort
- Other herbal preparations (such as garlic, ginseng, feverfew, ginkgo biloba and ginger)
- Drinking alcohol
- Cranberry and grapefruit juice
- Eating large amounts of green leafy vegetables and/or drastic changes in dietary habits.

These may be affected by COUMADIN or may affect how well COUMADIN works. You may need different amounts of these or you

may need to take something different.

There are various other medicines which interact with COUMADIN. Your doctor and pharmacist have a more complete list of medicines to avoid while taking COUMADIN.

If you have not told your doctor about any of these things tell him/her before you take COUMADIN.

How to take COUMADIN

How much to take

You should follow your doctor's directions exactly about how much COUMADIN to take.

Different people require different amounts of COUMADIN and the dosage is adjusted to suit each patient. Your directions should be printed on the pharmacy label.

By using the results of a blood test, your doctor will decide what amount of COUMADIN you need. This means that your doctor may sometimes change your dose of COUMADIN so that the dose is right for you.

Each tablet has a score or break line so that the tablets can be halved if needed to provide the exact dose your doctor has prescribed for you.

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 to take it

Swallow COUMADIN with a glass of water. Do not crush or chew the tablets.

How long to take it

You may not feel any differently while taking COUMADIN from the

way you were prior to taking it. However, COUMADIN will continue to be prescribed while there is a risk of excessive blood clotting.

Do not stop taking COUMADIN or reduce your dose unless your doctor advises you to do so.

If you forget to take COUMADIN

If you forget to take a dose of COUMADIN, tell your doctor immediately.

Take the dose as soon as you remember and then go back to taking it as you would normally.

However, if it is less than 12 hours till your next dose is due, skip the missed dose and take your next dose when you were meant to.

Do not try to make up for a missed dose by taking more than one dose per day.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

You should make a note in your warfarin treatment booklet/record of any missed or late doses. Tell your doctor or nurse about the missed or late doses at your next blood appointment. If you are worried you should contact your doctor or nurse for any advice on increased monitoring requirements.

If you have trouble remembering when to take COUMADIN, ask your pharmacist for some hints.

While you are taking COUMADIN

Things you must do

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

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. 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.

It is recommended that you carry identification with you, stating that you are taking COUMADIN.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if for any reason you have not taken your COUMADIN as prescribed, otherwise your doctor may make unnecessary changes to your dose.

Eat a normal balanced diet and do not make any big changes in your diet. This minimises the possibility of your dietary habits interfering with COUMADIN.

Things you must not do

Do not take COUMADIN to treat any other complaints other than that directed by your doctor. It may not be safe to take COUMADIN for another complaint.

Do not give your medicine to anyone else, even if they have the same condition as you. It may not be safe to take COUMADIN for another complaint.

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

Do not stop or start any other medicines without checking with your doctor. This includes medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Things to be careful of

There are two brands of warfarin tablets. One is COUMADIN and the other is MAREVAN. Do not change from one brand to the other. It may not be safe to change

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

Symptoms of an overdose may include noticeable or abnormal bleeding such as blood in bowel motions or urine, heavy menstrual bleeding, unusual bruising, continual oozing of blood from surface injuries

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COUMADIN, even if you do not think the problem is connected with COUMADIN or if it is not listed in this leaflet.

This medicine helps most people, but it may have unwanted side effects in a few people.

Early notification to your doctor about such effects can help prevent more serious complications by allowing for prompt adjustments in your COUMADIN therapy.

Tell your doctor or pharmacist if you notice any of the following and they worry you, particularly if they remain or get worse over time:

- Nausea, vomiting and/or diarrhoea
- Hair loss
- Skin rash
- Fever

- Prolonged, and sometimes painful erection (priapism)

The above list includes some side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- Unexplained bruising or pinpoint red spots on your skin
- Pink, red or dark brown urine (this may be due to bleeding in the bladder or kidneys)
- Red or black tarry bowel motions
- Unexplained nose bleeds or bleeding gums
- Vomiting or coughing up blood or particles that look like coffee grounds (signs of bleeding in the stomach or intestines)
- Prolonged bleeding or oozing blood from cuts and wounds
- Unusually heavy periods or bleeding from the vagina
- Blurred vision, slurred speech, loss of movement, numbness, dizziness, headache, nausea, vomiting, fits, loss of consciousness as these could be the sign of a bleed in the brain
- Yellowing of skin or whites of eyes
- Painful blue/purple or mottled toes
- Swollen ankles
- Painful swelling or discomfort
- Stomach pain
- Chest Pain
- Joint Pain
- Painful skin rash
- Severe skin wounds
- Persistent diarrhoea
- A serious fall or injury.

The above list includes side effects that which may indicate your clotting levels are too low and that your dose needs to be changed. These side effects may require medical attention.

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

- Signs of an allergic reaction which include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare

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 side effects.

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

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

After taking COUMADIN

Storage

Keep your tablets in the bottle until it is time to take them

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 30°C.

Do not store COUMADIN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

COUMADIN tablets are available in 3 different strengths:

Each strength has a different colour so it is easy to tell them apart. Be sure you are taking the right tablet by checking the colour and strength.

COUMADIN 1mg is a round light tan tablet with a score or break line on one side with COUMADIN above the break line and a '1' below the break line.

COUMADIN 2mg is a round lavender tablet with a score or break line on one side with COUMADIN above the break line and a '2' below the break line.

COUMADIN 5mg is a round green tablet with a score or break line on one side with COUMADIN above the break line and a '5' below the break line.

Each bottle of COUMADIN tablets contains 50 tablets.

Ingredients

Active ingredient(s):

COUMADIN tablets contain either 1mg, 2 mg or 5mg warfarin as the active ingredient.

Inactive ingredient(s):

- Lactose anhydrous
- Maize starch
- Stearic acid
- Magnesium stearate
- Amaranth ((123) in COUMARIN 1mg and 2 mg only)
- Indigo carmine (132) in COUMARIN 2 mg only

- Brilliant blue FCF (133) in Coumarin 5 mg only
- Quinoline yellow (104) in COUMARIN 1 mg and 5mg only

This medicine does not contain sucrose, gluten or tartrazine.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

COUMADIN is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

26 September 2019.
(Based on Coumadin datasheet dated 26 September 2019)