

COUMADIN

warfarin sodium

Consumer Medicine Information

What is in this leaflet

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 the active ingredient warfarin. This type of medication is known as an anticoagulant. Some people refer to anticoagulant medicines as “blood thinners”.

It helps to prevent blood from excessive clotting or forming harmful clots. 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There are two brands of warfarin. They are called COUMADIN and MAREVAN. Do not swap from one brand to the other.

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

Before you use it

When you must not use it

Do not take COUMADIN if you have an allergy to:

- any medicine containing warfarin
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may 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

Do not take COUMADIN if you are pregnant.

It may affect your developing baby.

Do not breast-feed if you are taking this medicine.

The active ingredient in COUMADIN passes into breast milk and there is a possibility that your baby may be affected.

Do not take COUMADIN if you tend to bleed easily, have any active ulcers or have abnormal blood cells.

This medicine may make bleeding tendencies worse.

Do not take COUMADIN if you have moderate to severe high blood pressure.

The risk of bleeding in may be increased by taking this medicine.

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 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 small intestine (duodenum)
- red or black bowel motions
- bleeding tendencies
- fits or convulsions
- thyroid problems
- heart problems
- psychiatric problems
- severe diabetes
- long-lasting infections, diarrhoea, vomiting or fever
- alcoholism
- severe allergies

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

Tell your doctor if you:

- are going to have any dental treatment
- have recently had or are going to undergo any surgical procedures or operations
- are starting any sporting activities that may result in traumatic injury

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and foods and COUMADIN may interfere with each other. These include:

- aspirin
- any medication used to treat arthritis (including glucosamine and chondroitin)
- some medications used to treat blood clots, heart attacks or angina
- antihistamines or any cough or cold preparations
- some antibiotics
- laxatives
- vitamin C
- vitamin E
- 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 medicines may be affected by COUMADIN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take COUMADIN

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

Follow your doctor's directions exactly about how much COUMADIN to take.

Different people require different amounts of this medicine and the dosage is adjusted to suit you.

Your doctor will determine how much to take through blood tests. It is important to keep all of your doctor's appointments so that your progress can be checked.

How to take it

Swallow the tablets whole with a glass of water.

Do not crush or chew the tablets.

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.

This medicine helps to control your condition, but does not cure it.

Do not stop taking COUMADIN or reduce your dose unless your doctor tells you to.

If you forget to take it

If it is less than 8 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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.

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, 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.

Possible signs of overdose include bleeding. Blood may also be seen in stools or urine. Abnormal bruising or abnormal menstrual bleeding may also be experienced.

While you are using COUMADIN

Things you must do

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

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

Try to eat a balanced diet.

This minimises the possibility of the food you eat interfering with COUMADIN.

Things you must not do

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

Do not start or stop taking any other medicines whilst you are taking COUMADIN unless you have spoken to your doctor.

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.

There are two brands of warfarin called COUMADIN and MAREVAN. Do not swap from one brand to the other.

Things to be careful of

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

Do not drink alcohol while you are taking this medicine.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

This medicine helps most people with excessive clotting, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- bruising
- nosebleeds
- bleeding from gums after brushing
- increased menstrual flow or heavier periods
- purplish & mottled toes
- prolonged bleeding from cuts
- swollen ankles
- painful swelling or discomfort
- stomach pain
- joint pain

- persistent headache or fever
- non-healing wounds or lesions or mottling of skin

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

- red or dark brown urine
- persistent diarrhoea
- red or black bowel motions
- vomiting or coughing up blood
- chest pain
- difficulty breathing or swallowing
- severe skin wounds
- a serious fall or injury

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

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.

After using 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. Keep the tablets away from light.

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 ruin 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 1 mg tablets are light tan, scored and embossed with “1” below the score line and “COUMADIN” above. The other side is plain.

COUMADIN 2 mg tablets are lavender, scored and embossed with “2” below the score line and “COUMADIN” above. The other side is plain.

COUMADIN 5 mg tablets are green, scored and embossed with “5” below the score line and “COUMADIN” above. The other side is plain.

COUMADIN is available in bottles containing 50 tablets.

Ingredients

COUMADIN contains either 1 mg, 2 mg or 5 mg of warfarin sodium as the active ingredient.

The tablets also contain the following inactive ingredients:

- lactose
- magnesium stearate
- maize starch
- stearic acid
- amaranth (1 mg and 2 mg only)
- indigo carmine (2 mg only)
- brilliant blue FCF (5 mg only)
- quinoline yellow (1 mg & 5 mg only)

The tablets contain sulfites and sugars (as lactose).

Distributor

Mylan Health Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au
Phone: 1800 314 527

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COUMADIN 1 mg: AUST R 42269

COUMADIN 2 mg: AUST R 14937

COUMADIN 5 mg: AUST R 42279

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