

# COUMADIN®

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## 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.

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### 1. Why am I using COUMADIN?

COUMADIN contains the active ingredient warfarin. COUMADIN is used to prevent blood from excessive clotting or forming harmful clots. For more information, see Section [1. Why am I using COUMADIN?](#) in the full CMI.

### 2. What should I know before I use COUMADIN?

Do not use if you have ever had an allergic reaction to COUMADIN 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 use COUMADIN?](#) in the full CMI.

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### 3. What if I am taking other medicines?

Some medicines may interfere with COUMADIN 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 use COUMADIN?

- 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.
- COUMADIN should be taken at about the same time each day.

More instructions can be found in Section [4. How do I use COUMADIN?](#) in the full CMI.

### 5. What should I know while using COUMADIN?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using COUMADIN.
- If you are going to have surgery, tell the surgeon

	<p>or anaesthetist that you are taking this medicine.</p> <ul style="list-style-type: none"> <li>● If you become pregnant while taking this medicine, tell your doctor immediately.</li> <li>● If you are about to have any blood tests, tell your doctor that you are taking this medicine.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not stop taking your medicine or lower the dosage without checking with your doctor.</li> <li>● There are two brands of warfarin called COUMADIN and MAREVAN. Do not swap from one brand to the other.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools until you know how COUMADIN affects you.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● Do not drink alcohol while you are taking this medicine.</li> <li>● Tell your doctor if you drink alcohol.</li> </ul>

### Looking after your medicine

- 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.

For more information, see Section [5. What should I know while using COUMADIN?](#) in the full CMI.

## 6. Are there any side effects?

Speak to your doctor as soon as possible if you notice any of the following side effects, bruising, nosebleeds, and bleeding from gums after brushing. Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of the following serious side effects, blood in urine, chest pain, difficulty breathing or swallowing and severe skin wounds.

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.

# COUMADIN®

**Active ingredient(s):** *warfarin sodium*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using COUMADIN. **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 COUMADIN.**

**Where to find information in this leaflet:**

- [1. Why am I using COUMADIN?](#)
- [2. What should I know before I use COUMADIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use COUMADIN?](#)
- [5. What should I know while using COUMADIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using COUMADIN?

**COUMADIN contains the active ingredient warfarin.** COUMADIN is an anticoagulant. Some people refer to anticoagulant medicines as “blood thinners”.

**COUMADIN is used 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.**

**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.**

## **2. What should I know before I use COUMADIN?**

### **Warnings**

#### **Do not use COUMADIN if:**

- you are allergic to warfarin, or 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
- Always check the ingredients to make sure you can use this medicine.
- 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 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.

### **Check with your doctor if you:**

- have or have had any of the following medical conditions:
  - liver or intestinal disease such as coeliac disease
  - kidney disease or impaired kidney function
  - 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.
- take any medicines for any other condition

- have allergies to any other medicines, foods, preservatives or dyes.
- 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.

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**

Check with your doctor if you are pregnant or intend to become pregnant.

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

**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.



### **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.

**Some medicines and foods may interfere with COUMADIN and affect how it works. 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.

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

## **4. How do I use COUMADIN?**

### **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 your doctor's appointments so that your progress can be checked.
- Follow the instructions provided by your doctor or pharmacist and use COUMADIN until your doctor tells you to stop.
- 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.
- 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.

### **When to take COUMADIN**

- COUMADIN should be taken 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 COUMADIN**

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

## **If you forget to use COUMADIN**

COUMADIN should be used regularly at the same time each day.

**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 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 use too much COUMADIN**

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

### **You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.**

**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.**

## **5. What should I know while using COUMADIN?**

### **Things you should do**

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

**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.**

**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.**

**Try to eat a balanced diet.**

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

**Call your doctor straight away if you:**

- do not feel well while you are taking COUMADIN.

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

**Things you should 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.

## **Driving or using machines**

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

COUMADIN may cause dizziness in some people

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

## **Looking after your medicine**

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

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.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

**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.**

## **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
<ul style="list-style-type: none"><li>• bruising</li><li>• nosebleeds</li><li>• bleeding from gums after brushing</li><li>• increased menstrual flow or heavier periods</li><li>• purplish &amp; mottled toes</li><li>• prolonged bleeding from cuts</li><li>• swollen ankles</li><li>• painful swelling or discomfort</li><li>• stomach pain</li><li>• joint pain</li><li>• persistent headache or fever</li><li>• non-healing wounds or lesions or mottling of skin</li></ul>	<p><b>Speak to your doctor as soon as possible if you notice any of the following</b></p>



## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● red or dark brown urine</li><li>● symptoms related to a condition called anticoagulant-related nephropathy: blood in urine, reduced urine output, swelling of the legs, ankles and feet, increased time for blood to clot (high INR test values), heavy bleeding</li><li>● persistent diarrhoea</li><li>● red or black bowel motions</li><li>● vomiting or coughing up blood</li><li>● chest pain</li><li>● difficulty breathing or swallowing</li><li>● severe skin wounds</li><li>● a serious fall or injury</li></ul>	<p><b>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.</b></p>

**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.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). 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 COUMADIN contains

<b>Active ingredient (main ingredient)</b>	COUMADIN 1 mg - 1 mg warfarin sodium COUMADIN 2 mg - 2 mg warfarin sodium COUMADIN 5 mg - 5 mg warfarin sodium
<b>Other ingredients (inactive ingredients)</b>	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)
<b>Potential allergens</b>	sugars as lactose and sulfites

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

### **What COUMADIN 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 (AUST R 42269).

COUMADIN 2 mg tablets are lavender, scored and embossed with “2” below the score line and “COUMADIN” above. The other side is plain (AUST R 14937).

COUMADIN 5 mg tablets are green, scored and embossed with “5” below the score line and “COUMADIN” above. The other side is plain (AUST R 42279).

COUMADIN is available in bottles containing 50 tablets.

## **Who distributes COUMADIN**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

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