

COUMADIN

Warfarin Sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions asked about COUMADIN. It does not contain all the available information about COUMADIN. This leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed up the risks of you taking COUMADIN against the expected benefits.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again later.

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 type of medication is called an *anticoagulant*. Some people refer to anticoagulant medicines 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. They are called COUMADIN and MAREVAN. Do not swap from one brand to the other. You should not combine these brands.

There is no evidence that COUMADIN is addictive.

COUMADIN is only available with a doctor's prescription.

Before you use COUMADIN

When you must not use it

Do not take COUMADIN during pregnancy.

Taking COUMADIN during pregnancy may harm the developing baby. If you are considering becoming pregnant or it is possible for you to become 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 had an allergic reaction to:

- Warfarin
- Any of the other 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 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 COUMADIN after the expiry date (EXP) printed on the bottle.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

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/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
- Long-lasting infections, diarrhoea, vomiting or fever
- Alcoholism
- Severe allergies

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 medications, including those you might buy from a chemist, health food shop or supermarket.

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

- Aspirin
- Any medication used to treat arthritis
- Some medications used to treat blood clots or heart attacks
- Antihistamines or any cough or cold preparations
- Some antibiotics
- Laxatives
- Vitamin C
- Vitamin E
- Vitamin K
- St John's Wort
- Drinking alcohol
- Cranberry 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 to take different amounts of these or you may need to take something different.

Your doctor or pharmacist has 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 alter your dose of COUMADIN so that your dose is right 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.

How to take it

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

It does not matter if you take COUMADIN before or after food.

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 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 almost time for your next dose (eg. within 8 hours), 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.

If you have trouble remembering when to take COUMADIN, 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) or go to the casualty department at your nearest hospital if you think that you or anyone else may have taken too much COUMADIN, even if there are no signs of discomfort or poisoning. Keep the telephone numbers for your doctor, the Poisons Information Centre and your nearest hospital handy so that they are accessible in case of an emergency.

Possible signs of taking too many COUMADIN tablets include bleeding. Blood may 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

Make sure that all of the doctors, dentists and pharmacists that are treating you know that you are taking COUMADIN. It is recommended that you also carry identification stating that you are taking COUMADIN.

Tell your doctor immediately if you become pregnant while taking COUMADIN.

Tell your doctor if, for any reason, you have not taken COUMADIN exactly as prescribed.

Otherwise your doctor may think that COUMADIN was not effective and change

your treatment unnecessarily.

Be sure to keep all of your appointments for blood tests so that the effect of COUMADIN can be checked.

Eat a normal, balanced diet.

This minimises the possibility of dietary habits interfering with COUMADIN.

Things you must not do

Do not start or stop any other medicines while you are taking COUMADIN unless you have discussed this with your doctor.

This includes medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

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

It may not be safe to change between these brands.

Do not take COUMADIN to treat any complaint other than that directed by your doctor.

It may not be safe to take COUMADIN for another complaint.

Do not give COUMADIN to anyone else, even if their symptoms seem similar.

It may not be safe for another person to take COUMADIN.

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 it is not listed in this leaflet.

COUMADIN helps most people, but it may have unwanted side effects in some people.

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

All medicines can have side effects. Medical treatment may be required for some side effects.

If any of the following occur after taking COUMADIN, immediately contact your doctor or the casualty department at your nearest hospital:

- Bruising
- Red or dark brown urine
- Red or black bowel motions
- Nosebleeds
- Bleeding from gums after brushing
- Vomiting or coughing up blood
- Increased menstrual flow or heavier periods
- Purplish & mottled toes
- Prolonged bleeding from cuts
- Swollen ankles
- Painful swelling or discomfort
- Stomach pain

- Chest pain
- Joint pain
- Persistent headache or fever
- Difficulty breathing or swallowing
- Severe skin wounds
- Persistent diarrhoea
- A serious fall or injury

These are serious side effects. Urgent medical attention may be required to deal with these effects.

Tell your doctor or pharmacist if any other side effects occur while taking COUMADIN.

Other side effects not listed above may also occur in some people. If this occurs, continue to take COUMADIN unless your doctor or pharmacist advises otherwise.

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

After using COUMADIN

Storage

Keep COUMADIN in the bottle until it is time to take it.

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

Do not store COUMADIN, or any other medicines, in the bathroom or near a sink.

Heat and dampness can ruin some medicines.

Keep COUMADIN in a cool, dry place where the

temperature stays below 30°C.

Do not leave the tablets in the car or on a windowsill on hot days.

Keep it where young 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 COUMADIN, or you find that they have passed their expiry date, ask your pharmacist what to do with any unused medicine left over.

Product Description

What it looks like

COUMADIN tablets are available in three different strengths.

Each strength has a separate colour to distinguish it from the others. Be sure you are taking the right tablet by checking the colour and strength.

Each strength appears as follows:

- 1 mg: round, light tan, scored, marked "1" and COUMADIN on one side and plain on the other.
- 2 mg: round, lavender, scored, marked "2" and "COUMADIN" on one side and plain on the other.
- 5 mg: round, green, scored, marked "5" and

“COUMADIN” on one side and plain on the other.

Each bottle of COUMADIN contains 50 tablets.

Ingredients

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

The other ingredients in COUMADIN are:

- Lactose Anhydrous
- Starch - Tapioca
- Stearic Acid
- Magnesium Stearate (470)
- Amaranth (123) - COUMADIN 1 & COUMADIN 2 mg
- Indigo Carmine (132) - COUMADIN 2 mg
- Brilliant Blue FCF (133) - COUMADIN 5 mg
- Quinoline Yellow (104) - COUMADIN 1 mg & 5 mg

COUMADIN contains NO sucrose, gluten or tartrazine.

Croydon VIC 3136

Ph: (03) 9839 2800

COUMADIN Australian registration numbers:

- 1 mg tablets: AUST R 42269
- 2 mg tablets: AUST R 14937
- 5 mg tablets: AUST R 42279

This leaflet was updated in March 2005

Further Information

If you have any further questions or if you are not sure about anything relating to the use of COUMADIN, your doctor or pharmacist can best assist you.

Sponsor

COUMADIN is supplied in Australia by:
Sigma Pharmaceuticals Pty Ltd (ACN 004 118 594)
96 Merrindale Drive