

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrCOUMADIN® Warfarin Sodium Tablets

Read this carefully before you start taking COUMADIN and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about COUMADIN.

Serious Warnings and Precautions

Risk of bleeding:

The most common side effect of COUMADIN is bleeding. The bleeding may be serious and life-threatening. You may be more at risk for bleeding if you have:

- a history of bleeding in your stomach or intestines (ulcers)
- high blood pressure
- heart disease
- problems with the blood circulation in your brain
- anemia
- cancer
- kidney disease
- experienced trauma or injury to your body.

Talk to your healthcare professional if you have any of the above conditions. You may also have a higher risk of bleeding if you take COUMADIN for a long time or if you take COUMADIN with certain other drugs. An INR level of 4.0 or greater is also a risk for bleeding. INR is a blood test that tells the level of blood clotting you have. Your healthcare professional will work to keep your INR within a range that is right for you. This will help lower the risk of bleeding. Notify your healthcare professional right away of any unusual bleeding or if signs or symptoms of bleeding occur (see “**What are possible side effects from using COUMADIN?**”).

What is COUMADIN used for?

- COUMADIN is an anticoagulant drug. “Anti” means against, and “coagulant” refers to blood clotting. An anticoagulant helps reduce clots from forming in the blood.
- COUMADIN is a narrow therapeutic index drug, which means that there is a narrow window between too much and too little of the drug. Too much drug may cause you to bleed more. Too little drug may let a harmful clot form.

How does COUMADIN work?

- COUMADIN partially blocks the re-use of vitamin K in your liver. Vitamin K is needed to make clotting factors. The clotting factors help the blood to clot and prevent bleeding. Vitamin K is found naturally in foods such as leafy, green vegetables and certain vegetable oils.

- COUMADIN begins to reduce blood clotting within 24 hours after taking the drug. The full effect may take 72 to 96 hours to occur. The anti-clotting effects of a single dose of COUMADIN last 2 to 5 days, but it is important for you to take your dose every day.

What are the ingredients in COUMADIN?

Medicinal ingredient: warfarin sodium

Non-medicinal ingredients: lactose anhydrous, magnesium stearate, pregelatinized tapioca starch, and colour dye which varies in each tablet strength:

- 1.0 mg: Pink color - D&C Red No. 6 Barium Lake
- 2.0 mg: Lavender color - FD&C Blue No. 2 Aluminum Lake and FD&C Red No. 40 Aluminum Lake
- 2.5 mg: Green color - FD&C Blue No. 1 Aluminum Lake and D&C Yellow No. 10 Aluminum Lake
- 3.0 mg: Tan color - FD&C Yellow No. 6 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake and FD&C Red No. 40 Aluminum Lake
- 4.0 mg: Blue color - FD&C Blue No. 1 Aluminum Lake
- 5.0 mg: Peach color - FD&C Yellow No. 6 Aluminum Lake
- 6.0 mg: Teal color - FD&C Yellow No. 6 Aluminum Lake and FD&C Blue No. 1 Aluminum Lake
- 10.0 mg: White color - Dye free

COUMADIN comes in the following dosage forms:

COUMADIN tablets are available in 1 mg, 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg and 10 mg strengths.

Do not use COUMADIN if:

- you are pregnant, in particular if you have a high risk pregnancy. Use effective measures to avoid pregnancy while taking COUMADIN. This is very important because your unborn baby could be seriously harmed if you take COUMADIN while you are pregnant. Your baby could be born with birth defects or could die.
- you have recently had or are planning to have surgery of the eyes, central nervous system, or any major surgery.
- you have certain conditions such as:
 1. stomach or intestinal bleeding or ulcers
 2. bleeding in the lungs or kidneys, bladder or urethra
 3. cerebral hemorrhage (bleeding in the brain)
 4. heart infection
 5. swelling of the heart membrane or fluid in the heart
 6. a brain aneurysm (swelling of an artery that supplies blood to the brain).
- you have any medical procedure that can increase the risk of bleeding, such as spinal puncture or spinal anesthesia.
- you have severe uncontrolled high blood pressure.

- you are allergic to warfarin or any of the other ingredients in COUMADIN (see **What are the ingredients in COUMADIN?**).
- you consume alcohol.
- you practice any activity or sport that may result in serious injury.
- have psychosis (a mental disorder).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take COUMADIN. Talk about any health conditions or problems you may have, including if you:

- fall often
- have liver or kidney problems or a heart problem called congestive heart failure
- have high blood pressure
- have diabetes
- have a low blood count
- have cancer
- have a history of stroke or “mini-stroke” (transient ischemic attack)
- drink alcohol or have problems with alcohol abuse. Alcohol can affect your COUMADIN dose and should be avoided
- plan to have any surgery or a dental procedure. Tell all of your healthcare professionals and dentists that you are taking COUMADIN. They should talk to the healthcare professional who prescribed COUMADIN for you. This should be done before you have **any** surgery or dental procedure. Your COUMADIN may need to be stopped for a short time or you may need your dose adjusted
- are pregnant or planning to become pregnant Do not take COUMADIN during pregnancy. Use effective measures to avoid pregnancy while taking COUMADIN. This is very important because your unborn baby could be seriously harmed if you take COUMADIN while you are pregnant. Your baby could be born with birth defects or could die.
- are breastfeeding. COUMADIN may cause your baby to bleed. Talk to your healthcare professional about the best way to feed your baby. If you choose to breastfeed while taking COUMADIN, both you and your baby should be carefully monitored for bleeding problems

Other warnings you should know about:

- **Death of skin tissue (skin necrosis or gangrene).** This can happen soon after starting COUMADIN. It happens because blood clots form and block blood flow to an area of your body. You may need medical care right away to prevent death or loss (amputation) of your affected body part.
- COUMADIN may cause calcium build up in small blood vessels of the fat and skin tissues (calciphylaxis). This can cause hardening of your blood vessels.
- COUMADIN may cause pain in your toes. Your toes may look purple or dark in color. (**“Purple toes syndrome”**). This is due to the blood thinning effect of COUMADIN, which can cause the release of plaques that can block an artery. You may also experience other symptoms such as rash, gangrene (lack of blood supply to a body part), intense pain in the leg, foot, toes, back or in your side. You may need medical care right away to prevent death or loss (amputation) of your affected body part.

- COUMADIN should not be used if you have low platelet levels (**thrombocytopenia**) as this can be serious or life-threatening.
- **Blood Testing:**
 - To decide on the dosage of COUMADIN you need, your healthcare professional will regularly take a small amount of your blood. This will help to find out how fast your blood clots. This is often recorded as an INR (International Normalized Ratio). INR tests are very important. They help your healthcare professional determine what dosage of COUMADIN is right for you.
 - ⊖ When you start taking COUMADIN, you may have INR tests every day for a few days, then periodically on a regular basis. Your healthcare professional will determine how often you need to have these tests done. **These INR tests and regular visits to a healthcare provider are very important for the success of COUMADIN therapy.** You will need to have these tests on a regular basis while you take COUMADIN. This will help keep your INR in the best range for your medical condition. Discuss with your healthcare professional the range that is right for you.
- Certain illnesses can affect your COUMADIN therapy. Call your health professional if you:
 - are throwing up
 - have loose or runny stools
 - have an infection
 - have a fever.
- Carry identification stating that you are taking COUMADIN.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Some of your other medicines may affect the way COUMADIN works. Certain medicines may increase your risk of bleeding.

The following prescription medicines may interact with COUMADIN:

- Medicines to treat pain and inflammation called Non-steroidal anti-inflammatories (NSAIDs) such as ibuprofen, celecoxib, diclofenac and naproxen.
- Blood thinners such as aspirin, clopidogrel, apixaban, rivaroxaban, dabigatran, ticagrelor, prasugrel and dipyridamole.
- Antidepressants in the class called selective serotonin reuptake inhibitors (SSRI) such as sertraline, paroxetine, fluoxetine, escitalopram and citalopram.
- Medicines to treat bacterial or antifungal infections such as amoxicillin, penicillin, azithromycin, ciprofloxacin, erythromycin, doxycycline, fluconazole, voriconazole and itraconazole.
- Other medicines that contain warfarin. Warfarin is the active ingredient in COUMADIN.

Natural health products that may interact with COUMADIN include:

1. bromelains

2. coenzyme Q10
3. danshen (*Colocasia antiquorum*)
4. dong quai (*Angelica sinensis*)
5. garlic
6. ginkgo biloba
7. ginseng
8. St. John's wort

How COUMADIN may interact with food:

1. Eat a normal balanced diet. Avoid big changes in your diet. Talk to your healthcare professional **before** you go on a diet.
2. Eat a consistent amount of green, leafy vegetables. Do not make big changes in your diet. These vegetables have high amounts of Vitamin K. The amount of vitamin K in your daily diet may affect therapy with COUMADIN.
3. Tell your healthcare professional if cranberry juice or other cranberry products are part of your normal diet.

How to take COUMADIN:

1. Be sure to check that the tablet has "COUMADIN" written on one side and the correct numeric strength before you take it.
1. **Take COUMADIN exactly the way your healthcare professional tells you and take it at the same time every day.**
2. You can take COUMADIN either with food or on an empty stomach.
3. Your dosage may change from time to time depending on your response to COUMADIN.
4. Do not start, stop, or change any medicine except on advice of your healthcare professional.
 - The dose of COUMADIN may be different for each patient. For example, older patients (age 60 years of age or older) seem to respond more to COUMADIN. As your age increases, you may need a lower dose of COUMADIN. Your healthcare professional will monitor your INR levels and will decide what dose is best for you. This dose may change from time to time.

Overdose:

If you think you have taken too much COUMADIN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

1. If you miss a dose of COUMADIN, notify your healthcare professional right away.
2. Take the dose as soon as possible on the same day,
3. Do not take a double dose of COUMADIN the next day to make up for a missed dose.

What are possible side effects from using COUMADIN?

These are not all the possible side effects you may feel when taking COUMADIN. If you experience any side effects not listed here, contact your healthcare professional.

COUMADIN affects blood clotting, so most side effects are related to bleeding. COUMADIN can cause bleeding that can be serious and sometimes lead to death.

Your healthcare professional will work to keep your INR within a range that is right for you. This will help lower the risk of bleeding.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Bleeding from your nose		X	
Bleeding of gums when brushing your teeth		X	
Coughing up blood.		X	
Unusual bruising (black-and-blue marks on your skin) for unknown reasons.		X	
Headache, dizziness, or weakness fatigue, feeling tired, general feeling of illness (malaise) - (Anemia).		X	
Bleeding from shaving or other cuts that do not stop.		X	
Unusual pain or swelling.		X	
• Pink or dark brown urine.		X	
UNCOMMON			
Allergic reactions: rash, itching, hives, trouble breathing, throat tightening or constriction, swelling of the face, lips or tongue, sudden low blood pressure.			X
Unexpected bleeding from the vagina.		X	
Bleeding in the brain: blurred vision, slurred speech, loss of movement, numbness, dizziness, headache, fits, loss of consciousness.			X
Vomiting blood or your vomit looks like coffee grounds.		X	
• Blood in your stool: Red or black stools that may look like tar.		X	
RARE			
Any sores, changes in skin color or temperature, or severe pain on your skin. (Skin necrosis - death of skin tissue).		X	
VERY RARE			
Purplish skin discoloration, pain in the foot and leg, tingling sensation in the foot. (Purple toe syndrome).		X	
More bleeding than usual when you get your menstrual period.		X	
UNKNOWN		X	

Changes in skin color or temperature, or severe pain on your skin. Calcium accumulation in small blood vessels of the fat and skin tissues (calciphylaxis).			
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These are not all of the side effects of COUMADIN. For more information, ask your healthcare professional or pharmacist.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect \(http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php\)](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) ;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) .

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

1. Store the tablets at room temperature (15°C to 30°C).
2. Protect from light and moisture.
3. Keep out of reach and sight of children.

If you want more information about COUMADIN:

1. Talk to your healthcare professional.
2. Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website \(http://hc-sc.gc.ca/index-eng.php\)](http://hc-sc.gc.ca/index-eng.php); the manufacturer's website at <http://www.bmscanada.ca>, or by calling 1-866-463-6267.

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