

MEDICATION GUIDE

COUMADIN[®] (COU-ma-din) Tablets (Warfarin Sodium Tablets, USP) Crystalline

Read this Medication Guide before you start taking COUMADIN (Warfarin Sodium) and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about COUMADIN when you start taking it and at regular checkups.

What is the most important information I should know about COUMADIN?

- **Take your COUMADIN exactly as prescribed to lower the chance of blood clots forming in your body.** (See “What is COUMADIN?”)
- **COUMADIN is very important for your health, but it can cause serious and life-threatening bleeding problems.** To benefit from COUMADIN and also lower your chance for bleeding problems, you must:
 - **Get your regular blood test to check for your response to COUMADIN.** This blood test is called a PT/INR test. The PT/INR test checks to see how fast your blood clots. Your healthcare provider will decide what PT/INR numbers are best for you. Your dose of COUMADIN will be adjusted to keep your PT/INR in a target range for you.
 - **Call your healthcare provider right away if you get any of the following signs or symptoms of bleeding problems:**
 - pain, swelling, or discomfort
 - headaches, dizziness, or weakness
 - unusual bruising (bruises that develop without known cause or grow in size)
 - nosebleeds
 - bleeding gums
 - bleeding from cuts takes a long time to stop
 - menstrual bleeding or vaginal bleeding that is heavier than normal
 - pink or brown urine
 - red or black stools
 - coughing up blood

- vomiting blood or material that looks like coffee grounds
- **Many other medicines, including prescription and non-prescription medicines, vitamins and herbal supplements can interact with COUMADIN and:**
 - **affect the dose you need, or**
 - **increase COUMADIN side effects.**

Tell your healthcare provider about all the medicines, vitamins, and herbal supplements you take. Do not stop medicines or take anything new unless you have talked to your healthcare provider. Keep a list of your medicines with you at all times to show your healthcare provider and pharmacist.

- **Do not take other medicines that contain warfarin. Warfarin is the active ingredient in COUMADIN.**
- **Some foods can interact with COUMADIN and affect your treatment and dose.**
 - **Eat a normal, balanced diet.** Talk to your doctor before you make any diet changes. **Do not eat large amounts of leafy green vegetables.** Leafy green vegetables contain vitamin K. Certain vegetable oils also contain large amounts of vitamin K. Too much vitamin K can lower the effect of COUMADIN.
 - **Avoid drinking cranberry juice or eating cranberry products.**
 - **Avoid drinking alcohol.**
- **Always tell all of your healthcare providers that you take COUMADIN.**
- **Wear or carry information that you take COUMADIN.**

What is COUMADIN?

COUMADIN is an anticoagulant medicine. It is used to lower the chance of blood clots forming in your body. Blood clots can cause a stroke, heart attack, or other serious conditions such as blood clots in the legs or lungs.

Who should not take COUMADIN?

Do not take COUMADIN if:

- **your chance of having bleeding problems is higher than the possible benefit of treatment.** Your healthcare provider will decide if COUMADIN is right for you. Talk to your healthcare provider about all of your health conditions.

- **you are pregnant or plan to become pregnant.** COUMADIN can cause death or birth defects to an unborn baby. Use effective birth control if you can get pregnant.
- **you are allergic to warfarin or to anything else in COUMADIN.**

What should I tell my healthcare provider before starting COUMADIN?

Tell your healthcare provider about all of your health conditions, including if you:

- **have bleeding problems**
- **fall often**
- **have liver or kidney problems**
- **have high blood pressure**
- **have a heart problem called congestive heart failure**
- **have diabetes**
- **drink alcohol or have problems with alcohol abuse.** Alcohol can affect your COUMADIN dose and should be avoided.
- **are pregnant or planning to become pregnant.** See “**Who should not take COUMADIN?**”
- **are breast-feeding.** COUMADIN may increase bleeding in your baby. Talk to your doctor about the best way to feed your baby. If you choose to breast-feed while taking COUMADIN, both you and your baby should be carefully monitored for bleeding problems.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. See “What is the most important information I should know about COUMADIN?”

How should I take COUMADIN?

- **Take COUMADIN exactly as prescribed.** Your healthcare provider will adjust your dose from time to time depending on your response to COUMADIN.
- **You must have regular blood tests and visits with your healthcare provider to monitor your condition.**
- **Take COUMADIN at the same time every day.** You can take COUMADIN either with food or on an empty stomach.

- **If you miss a dose of COUMADIN, call your healthcare provider.** Take the dose as soon as possible on the same day. Do not take a double dose of COUMADIN the next day to make up for a missed dose.
- **Call your healthcare provider right away if you take too much COUMADIN.**
- **Call your healthcare provider if you are sick with diarrhea, an infection, or have a fever.**
- **Tell your healthcare provider about any planned surgeries, medical or dental procedures.** Your COUMADIN may have to be stopped for a short time or you may need your dose adjusted.
- **Call your healthcare provider right away if you fall or injure yourself, especially if you hit your head.** Your healthcare provider may need to check you.

What should I avoid while taking COUMADIN?

- Do not start, stop, or change any medicine without talking with your healthcare provider.
- Do not make changes in your diet, such as eating large amounts of green, leafy vegetables.
- Do not change your weight by dieting, without first checking with your healthcare provider.
- Avoid drinking alcohol.
- Do not do any activity or sport that may cause a serious injury.

What are the possible side effects of COUMADIN?

- COUMADIN is very important for your health, but it can cause serious and life-threatening bleeding problems. See **“What is the most important information I should know about COUMADIN?”**
- **Serious side effects of COUMADIN also include:**
 - **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. Call your healthcare provider right away if you have pain, color, or temperature change to any area of your body. You may need medical care right away to prevent death or loss (amputation) of your affected body part.
 - **“purple toes syndrome.”** Call your healthcare provider right away if you have pain in your toes and they look purple in color or dark in color.

Other side effects with COUMADIN include allergic reactions, liver problems, low blood pressure, swelling, low red blood cells, paleness, fever, and rash. Call your healthcare provider if you have any side effect that bothers you.

These are not all of the side effects of COUMADIN. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store COUMADIN?

- Store COUMADIN at room temperature between 59° and 86°F. Protect from light.
- **Keep COUMADIN and all medicines out of the reach of children.**

General Information about COUMADIN

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use COUMADIN for a condition for which it was not prescribed. Do not give COUMADIN to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about COUMADIN. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about COUMADIN that was written for healthcare professionals.

If you would like more information, call 1-800-321-1335 and also speak with your health care provider.

Rx only

COUMADIN is distributed by:

Bristol-Myers Squibb Company

Princeton, New Jersey 08543 USA

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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