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COUMADIN[®] (Warfarin Sodium Tablets, USP) Crystalline:

What It Is and What It Does

What is COUMADIN[®]?

COUMADIN[®] is an anticoagulant. *Anti* means *against*, and *coagulant* refers to *blood clotting*. An anticoagulant helps reduce clots from forming in the blood.

Why do I need COUMADIN[®]?

Your doctor wants you to take COUMADIN[®] because your body may make clots that you don't need. These clots can cause serious medical problems. A clot can move to another part of your body. For example, if a clot moves to your brain, it can cause a stroke.

COUMADIN[®] is used to help prevent and treat blood clots:

- in the legs and lungs
- associated with an irregular, rapid heartbeat called "atrial fibrillation"
- associated with heart-valve replacement

If you have had a heart attack, COUMADIN[®] may be used to:

- lower the risk of death
- lower the risk of another heart attack
- lower the risk of stroke
- lower the risk of blood clots moving to other parts of the body

How does COUMADIN[®] work?

- COUMADIN[®] blocks the formation of vitamin K-dependent clotting factors in your liver. Vitamin K is needed to make clotting factors that the blood to clot and prevent bleeding. Vitamin K is found naturally in foods such as leafy, green vegetables and certain vegetable oils.
- COUMADIN[®] reduces the body's ability to help make blood clots. It may help stop harmful clots from forming and keep clots from getting larger. **COUMADIN[®] does not break up existing blood clots.**
- COUMADIN[®] generally begins to reduce blood clotting within 24 hours after taking the drug. **The full effect may take 72 to 96 hours after dosing to occur.** The anticlotting effects of a single dose of COUMADIN[®] may last 2 to 5 days, but **it is important for you to take your dose as prescribed by your healthcare provider.**

If you have any other questions about COUMADIN[®] and your condition, contact your healthcare provider.

COUMADIN® (Warfarin Sodium Tablets, USP) Crystalline: How To Take It

How much do I take?

Your doctor determines how much COUMADIN® you need to take (your dosage) by giving you blood tests. The blood test is called a prothrombin time test, or protime (PT) for short, and is reported as **International Normalized Ratio (INR)**. Your dosage may change based on your PT/INR or other factors, so make sure you take the right dose of COUMADIN® daily.

When do I take it?

Try to take your COUMADIN® at the same time every day. Take it exactly the way your healthcare provider tells you. If you forget to take a pill, tell your healthcare provider immediately. Take the missed dose as soon as possible on the same day. **DO NOT take a double dose of COUMADIN®** the next day to make up for the missed dose. Will my dosage change?

Your dosage may change from time to time. Make sure you take the right dose on the right day, as your healthcare provider tells you.

COUMADIN® (Warfarin Sodium Tablets, USP) Crystalline: Blood Tests Why do I need blood tests?

To help your healthcare provider establish the dosage of COUMADIN® you need, your healthcare provider will take a small amount of your blood to find out your PT/INR. PT/INRs are very important. They help your healthcare provider determine how fast your blood is clotting and whether your dosage of COUMADIN® should change.

When will I have to take a PT/INR test?

When you start taking COUMADIN®, you may have PT/INR tests every day for a few days, then perhaps once every week. This will help your healthcare provider give you the dosage of COUMADIN® that is right for you.

PT/INR tests will be needed at periodic intervals throughout your course of therapy to help keep your PT/INR in the best range for your medical condition. It is important to follow the PT/INR schedule recommended by your healthcare provider.

What things may change my PT/INR test results?

Several factors, such as sickness, diet, other medicines (prescription and over-the-counter), or physical activities, may affect your PT/INR. Tell your healthcare provider about changes in your health, your medicines, or your lifestyle.

COUMADIN® (Warfarin Sodium Tablets, USP) Crystalline: Possible Side Effects and Drug Interactions

What are some possible side effects of COUMADIN®?

Your healthcare provider can tell you about possible side effects of COUMADIN®, which include bleeding and allergic reactions. The most common side effect and a serious risk

of COUMADIN[®] is bleeding in any tissue or organ. Numerous factors including travel, changes in diet, environment, general health, and medications, including botanicals (herbs), may affect your response to COUMADIN[®]. To lower the risk of bleeding, your PT/INR should be kept within a range that is right for you. Please contact your healthcare provider right away if you experience signs or symptoms of bleeding, such as:

- headache, dizziness, or weakness
- bleeding from shaving or other cuts that does not stop
- nosebleeds
- bleeding of gums when brushing your teeth
- throwing up blood
- unusual bruising (black-and-blue marks on your skin) for unknown reasons
- red or dark brown urine
- red or black color in your stool
- more bleeding than usual when you get your menstrual period or unexpected bleeding from the vagina
- unusual pain or swelling

Serious, but rare, side effects of COUMADIN[®] include skin necrosis (death of skin tissue) and "purple toes syndrome," either of which may require removal of unhealthy tissue and/or amputation of the affected area. Talk with your healthcare provider for further information on these side effects.

What should I know about drug interactions and diet?

COUMADIN[®] interacts with many drugs, including prescription and nonprescription (over-the-counter) drugs. **For this reason, it is important for you to check with your healthcare provider before starting, changing, or stopping any drug.** Some of the nonprescription drugs that may interact with COUMADIN[®] include: acetaminophen (Tylenol^{®*}); aspirin and aspirin-containing ointments and skin creams; ibuprofen (Motrin^{®*}, Advil^{®*}, Nuprin^{®*}); naproxen (Aleve^{®*}, Orudis KT^{®*}); H2-receptor antagonists, such as cimetidine (Tagamet^{®*}) or ranitidine (Zantac^{®*}); and vitamin supplements containing vitamin K. Other drugs may affect your response to COUMADIN[®]. Please check with your healthcare provider for additional information.

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Herbal medications may interact with COUMADIN[®]. Be aware that most herbal preparations are not standardized and potency may vary from one lot to another. Inform your healthcare provider if you intend to take herbal and/or natural products since you may need to be monitored more closely.

COUMADIN[®] (Warfarin Sodium Tablets, USP) Crystalline: Do's

What should I do?

Do take your COUMADIN[®] exactly as your healthcare provider tells you.

If you forget to take a tablet, do tell your healthcare provider immediately. Take the missed dose as soon as possible on the same day, but DO NOT take a double dose of COUMADIN[®] the next day to make up for the missed dose.

Do keep eating habits and activities similar every day.

Do get your blood tested when you are supposed to.

Do tell your healthcare provider about any other medicines you are taking (prescription and over-the-counter) and herbal/nutritional supplements. Also, ask your healthcare provider before you change, start, or stop taking any other medicines.

Do tell your healthcare provider when you get sick, get hurt, or get a cut that won't stop bleeding.

Do look for signs of bleeding. Tell your healthcare provider immediately. Your healthcare provider will decide if you need medical attention. (See the Possible Side Effects section on page 10.)

Do tell anyone giving you medical or dental care that you are taking COUMADIN®.

Carry identification stating that COUMADIN® is being taken.

Do refill your prescriptions according to your healthcare provider's instructions.

Do consider wearing a medical alert bracelet. (Ask your healthcare provider where you can get one.)

COUMADIN® (Warfarin Sodium Tablets, USP) Crystalline: Don'ts

What should I not do?

Do not take an extra tablet to catch up. If you forget to take a tablet, tell your healthcare provider immediately. Take the missed dose as soon as possible on the same day, but DO NOT take a double dose of COUMADIN® the next day to make up for the missed dose.

Do not take COUMADIN® if you are pregnant or plan on becoming pregnant. This is very important because COUMADIN® should not be taken during pregnancy. Tell your healthcare provider if you are or plan on becoming pregnant.

Do not take any other medicines before discussing with your healthcare provider.

Since COUMADIN® and generic warfarin have different tablet shapes and markings, there is a chance that you may take both products together by mistake. **Be aware that COUMADIN® and generic warfarin tablets represent the same medication and should not be taken together, as overdose may result.**

What should I avoid?

- avoid drastic changes in your dietary habits
- avoid alcohol consumption
- avoid any activity or sport that may result in a traumatic injury

COUMADIN® (Warfarin Sodium Tablets, USP) Crystalline: What If...?

What if COUMADIN® therapy is stopped?

If your healthcare provider stops your COUMADIN® therapy, the anticoagulant effects may last for about 2 to 5 days.

What if I want to travel while I take COUMADIN®?

You can travel, but tell your healthcare provider before you go. You may need to take a PT/INR test before you leave, or your healthcare provider may arrange for you to have one while on your trip. Remember to keep your eating habits and activity level as close

to your everyday routine as possible. Also, make sure to take enough COUMADIN[®] with you.

What if I want to participate in a sport or physical activity?

Ask your healthcare provider first. Your healthcare provider may want you to avoid any activity or sport that may result in a serious fall or other injury.

Why do I need to pay attention to my diet?

Many foods you eat have vitamin K in them, and vitamin K helps your body make clots. Food containing fat substitutes, such as olestra (Olean^{®*}), are supplemented with fat-soluble vitamins including vitamin K. These foods should be considered a source of vitamin K in the diet.

In addition, you may want to avoid herbal teas that have tonka beans, melilot (sweet clover), or sweet woodruff in them.

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Why should I stay on the same general diet every day?

Large changes in the amount of vitamin K you eat may affect your therapy with COUMADIN[®]. It is important for you to keep your diet consistent so the amount of vitamin K you eat is consistent. Please contact your healthcare provider before making major changes to your diet. Tell your healthcare provider if you change your diet because you are sick.

Should I avoid foods with a lot of vitamin K?

No. Just keep your diet consistent. Some foods that are important to a healthy diet are high in vitamin K, like leafy, green vegetables and some beans and peas.

The amount of vitamin K in food may affect therapy with COUMADIN[®]. Eat a normal, balanced diet maintaining a consistent amount of vitamin K. All foods are acceptable; however, avoid drastic changes in dietary habits. It is important to check with your healthcare provider before making any major changes to your diet. In general, leafy, green vegetables and certain legumes and vegetable oils contain high amounts of vitamin K. Foods that appear to contain low amounts of vitamin K include roots, bulbs, tubers, the fleshy portion of fruits, fruit juices, and other beverages. Likewise, cereal grains and their milled products appear to be low in vitamin K, as do most meats such as beef, chicken, pork, shrimp, tuna, and turkey. Be sure to ask your healthcare provider for "The Role of Vitamin K and COUMADIN[®] Use" patient information brochure. **Remember, it is more important that you keep your diet consistent.**

The following is a partial list of foods that contain medium (M) to high (H) levels of vitamin K:

Foods	Vitamin K ₁ Content
FATS AND DRESSINGS	
Margarine	M
Mayonnaise	H
Soybean, canola, and salad oils	H
Olive oil	M
VEGETABLES	
Asparagus	M
Avocado	M
Broccoli	H
Brussels sprouts	H
Cabbage	H
Cabbage, red	M
Collard greens	H
Endive (raw)	H
Green scallion (raw)	H
Kale leaf (raw)	H
Lettuce, bibb, red leaf (raw)	H
Lettuce, iceberg (raw)	M
Mustard greens (raw)	H
Parsley	H
Peas, green (cooked)	M
Spinach leaf (raw)	H
Turning greens (raw)	H
Watercress (raw)	H
CONDIMENT	
Dill pickle	M

COUMADIN[®] Uses

COUMADIN[®] (Warfarin Sodium Tablets, USP) Crystalline is used to help prevent and treat blood clots:

- In the legs and lungs
- Associated with an irregular, rapid heartbeat called "atrial fibrillation"
- Associated with heart-valve replacement

If you have had a heart attack, COUMADIN[®] may be used to:

- Lower the risk of death
- Lower the risk of another heart attack
- Lower the risk of stroke
- Lower the risk of blood clots moving to other parts of the body

Important Safety Information

The most common side effect of COUMADIN[®] is bleeding in any tissue or organ. Numerous factors including travel, changes in diet, environment, general health, and medication may affect your response to COUMADIN[®].

COUMADIN[®] should not be used when the hazard of bleeding might be greater than the potential clinical benefits of anticoagulation, such as:

- patients who are or may become pregnant
- blood diseases
- unsupervised patients with senility, alcoholism, psychosis, or other lack of cooperation
- procedures with potential for uncontrollable bleeding

COUMADIN[®] should be used with caution in patients who may be at risk of bleeding from trauma, surgery, or coadministration with NSAIDs including aspirin. Caution should be taken when administering to the elderly or debilitated.

Patients should be informed that all warfarin sodium, USP, products represent the same medication and should not be taken together as overdose may result.

If you have any other questions about COUMADIN[®] and your condition, contact your healthcare provider.

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