

INDICATIONS

What is COUMADIN[®] (warfarin sodium)?

- COUMADIN is used to help prevent and treat blood clots in the legs, lungs, and those clots associated with heart-valve replacement or an irregular, rapid heartbeat called atrial fibrillation.
- If you have had a heart attack, COUMADIN may be used to lower the risk of death, another heart attack, stroke, and blood clots moving to other parts of the body.
- It is not known if COUMADIN is safe and effective in children.

IMPORTANT SAFETY INFORMATION

COUMADIN can cause bleeding which can be serious and sometimes lead to death.

You may have a higher risk of bleeding if you take COUMADIN and:

- are 65 years old or older
- have a history of stomach or intestinal bleeding
- have high blood pressure (hypertension)
- have a history of stroke, or “mini-stroke” (transient ischemic attack or TIA)
- have serious heart disease
- have a low blood count or cancer
- have had trauma, such as an accident or surgery
- have kidney problems
- take other medicines that increase your risk of bleeding, including:
 - a medicine that contains heparin
 - other medicines to prevent or treat blood clots
 - non-steroidal anti-inflammatory drugs (NSAIDs)
- take warfarin sodium for a long time. Warfarin sodium is the active ingredient in COUMADIN.

Call your doctor or seek immediate medical care if you have any of the following signs or symptoms of bleeding:

- pain, swelling, or discomfort
- headaches, dizziness, or weakness
- unusual bruising (bruises that develop without known cause or grow in size)
- nosebleeds or 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 or vomiting blood; or vomiting material that looks like coffee grounds

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.** COUMADIN may cause birth defects, miscarriage, or death of your unborn baby. If you are **pregnant and have a mechanical heart valve**, talk to your doctor about whether the benefit of taking COUMADIN outweighs the risks
- **you are allergic to warfarin or any of the other ingredients in COUMADIN**

Please see additional Important Safety Information on page 2 and [U.S. Full Prescribing Information](#) including **Boxed WARNING** regarding bleeding risk and [Medication Guide](#) for COUMADIN.

IMPORTANT SAFETY INFORMATION (continued)

It is important to tell your healthcare provider about all prescription and non-prescription medicines, vitamins, and herbal supplements you take. Some of your medicines may affect the way COUMADIN[®] (warfarin sodium) works and affect the dose of COUMADIN you need or increase COUMADIN side effects.

- Do not change or stop any of your medicines or start any new medicines, vitamins, and herbal supplements without talking to your healthcare provider
- Do not take other medicines that contain warfarin sodium while taking COUMADIN.
- Get your regular blood test (INR) to check for your response to COUMADIN. The INR test checks to see how fast your blood clots. Your healthcare provider will decide what INR numbers are best for you and adjust your dose of COUMADIN to keep your INR in a target range.

Some foods and beverages can interact with COUMADIN and affect your treatment and dose.

- Eat a normal, balanced diet and talk to your healthcare provider before making any diet changes. Do not eat large amounts of leafy green vegetables, which contain vitamin K. Certain vegetable oils also contain large amounts of vitamin K. Too much vitamin K can lower the effect of COUMADIN

Before taking COUMADIN, tell your healthcare provider 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, or have any other medical conditions.
- are planning to have any surgery or dental procedure because you may have to stop taking COUMADIN for a short time or your dose may need to be adjusted.
- are pregnant or plan to become pregnant or considering breast-feeding while taking COUMADIN

Other possible serious side effects of COUMADIN 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 or dark in color.

Take COUMADIN exactly as prescribed by your doctor.

- Don't stop taking COUMADIN without talking to your doctor as your risk of stroke may increase
- Call your healthcare provider right away if you take too much COUMADIN, are sick with diarrhea, an infection, or have a fever, or fall or injure yourself, especially if you hit your head.

Please see [U.S. Full Prescribing Information](#) including **Boxed WARNING** regarding bleeding risk and [Medication Guide](#) for COUMADIN.

