

# COUMADIN® (warfarin sodium) tablets

## INDICATION

### What is COUMADIN?

COUMADIN is a prescription medicine used to treat blood clots and to lower the chance of blood clots forming in your body. Blood clots can cause a stroke, heart attack, or other serious conditions if they form in the legs or lungs.

## IMPORTANT SAFETY INFORMATION

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

COUMADIN can cause bleeding which can be serious and sometimes lead to death. This is because COUMADIN is a blood thinner medicine that lowers the chance of blood clots forming in your body.

- You may have a higher risk of bleeding if you take COUMADIN and:
  - are 65 years of age 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
    - nonsteroidal anti-inflammatory drugs (NSAIDs)
  - take warfarin sodium for a long time. Warfarin sodium is the active ingredient in COUMADIN

**Tell your healthcare provider if you take any of these medicines. Ask your healthcare provider if you are not sure if your medicine is one mentioned above.** Many other medicines can interact with COUMADIN, and affect the dose you need or increase COUMADIN side effects. Do not change or stop any medicines, or start new ones, before talking to your healthcare provider. **Do not take other medicines that contain warfarin sodium while taking COUMADIN.**

- **Get your regular blood test (INR test) to check for your response to COUMADIN,** 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 your target range.
- **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 that 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

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

## IMPORTANT SAFETY INFORMATION (continued)

- **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.

### Do not take COUMADIN if:

- **your risk of having bleeding problems is higher than the possible benefit of treatment.** Your healthcare provider will decide if COUMADIN is right for you.
- **you are pregnant unless you have a mechanical heart valve.** COUMADIN may cause birth defects, miscarriage, or death of your unborn baby.
- **you are allergic to warfarin or any of the other ingredients in COUMADIN.**

### Before taking COUMADIN, tell your healthcare provider about all of your medical conditions, including if you:

- have bleeding problems, fall often, have liver or kidney problems or are undergoing dialysis, have high blood pressure, have a heart problem called congestive heart failure, have diabetes.
- **are planning to have any surgery or dental procedure;** your COUMADIN may need to be stopped for a short time, or your dose adjusted.
- are pregnant or plan to become pregnant or are considering breastfeeding while taking COUMADIN.
  - Females who can become pregnant should use effective birth control during treatment, and for  $\geq 1$  months after the last dose of COUMADIN

**Tell your healthcare providers that you take COUMADIN, and about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how COUMADIN works, or may increase your risk of bleeding.

### COUMADIN may cause serious side effects including:

- **Death of skin tissue (skin necrosis or gangrene).** This can happen soon after starting COUMADIN, and 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 changes to any area of your body. You may need medical care right away to prevent death or loss (amputation) of your affected body part.
- **Kidney problems.** Kidney injury may happen in people who take COUMADIN. Tell your healthcare provider right away if there is blood in your urine. Your healthcare provider may do tests more often during treatment with COUMADIN to check for bleeding if you already have kidney problems.
- **"Purple toes syndrome."** Call your healthcare provider right away if you have pain in your toes and they look purple or dark in color.

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



