Understanding your COUMADIN therapy

Please see Indications and Important Safety Information on pages 14-15 and "What is the most important information I should know about COUMADIN?" for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
THIS BOOKLET IS ABOUT A MEDICINE CALLED COUMADIN

Please read this booklet because it answers many questions you may have about this medicine.

The first half of this booklet is the Medication Guide. It is the same Medication Guide that comes with your prescription for COUMADIN (Warfarin Sodium). It’s important to read it before you start taking COUMADIN. Whenever you refill COUMADIN, be sure to read the Medication Guide that comes with each refill. It may have new information.

The second half of this booklet, More About COUMADIN, has additional information in question and answer format to help you benefit from your treatment.

This booklet 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.

The information in this booklet has been developed and derived from over 50 years of experience with COUMADIN (Warfarin Sodium), the Bristol-Myers Squibb brand of warfarin sodium. Our intent is that this material should be used to assist with the management of patients on COUMADIN.

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Please see Indications and Important Safety Information on pages 14-15 and "What is the most important information I should know about COUMADIN?" for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT COUMADIN (Warfarin Sodium)?

- Take your COUMADIN exactly as prescribed to lower the chance of blood clots forming in your body. (See “What is COUMADIN?” on page 4)

- 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 (Warfarin Sodium) 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 grinds

- Many other medicines, including prescription and nonprescription medicines, vitamins, and herbal supplements can interact with COUMADIN (Warfarin Sodium) and:
  
  • affect the dose you need, or
  • increase COUMADIN side effects.

Please see Indications and Important Safety Information on pages 14-15 and “What is the most important information I should know about COUMADIN?” for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
WHAT IS COUMADIN (Warfarin Sodium)?
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 (Warfarin Sodium) 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 anything else in COUMADIN.
- you are taking other medicines that contain warfarin. Warfarin is the active ingredient in COUMADIN (Warfarin Sodium).
- 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 (Warfarin Sodium).
- Wear or carry information that you take COUMADIN.

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.

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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 (Warfarin Sodium)" on page 4)
- are breastfeeding. COUMADIN may increase bleeding in your baby. Talk to your doctor about the best way to feed your baby. If you choose to breastfeed while taking COUMADIN (Warfarin Sodium), 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?” on pages 3-4)

HOW SHOULD I TAKE COUMADIN?

- Take COUMADIN (Warfarin Sodium) 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 (Warfarin Sodium) 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 (Warfarin Sodium)?

- 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 (Warfarin Sodium)?

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?” on pages 3-4)

- 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.

Please see Indications and Important Safety Information on pages 14-15 and "What is the most important information I should know about COUMADIN?" for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
HOW SHOULD I STORE COUMADIN?

- Store COUMADIN at room temperature between 59° and 86°F. Protect from light.
- Keep COUMADIN (Warfarin Sodium) 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 (Warfarin Sodium) that was written for healthcare professionals.

If you would like more information, call 1-800-321-1335

- “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 (Warfarin Sodium). For more information, ask your healthcare provider or pharmacist.

Please continue reading this booklet for more about COUMADIN (Warfarin Sodium).

Please see Indications and Important Safety Information on pages 14-15 and “What is the most important information I should know about COUMADIN?” for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
**HOW DOES COUMADIN WORK?**

**Q**

Your liver makes clotting factors that help the blood clot and prevent bleeding. However, some blood clots can cause serious medical problems. COUMADIN (Warfarin Sodium) blocks the formation of clotting factors in the liver that are dependent on vitamin K, thus preventing the formation of blood clots.

**A**

Please read the following Questions and Answers for helpful information about COUMADIN (Warfarin Sodium) therapy.
**Q** HOW MUCH COUMADIN DO I TAKE?

**A** Your doctor determines how much COUMADIN you need (the dose and schedule) by giving you regular blood tests. Your dosage may change over time, depending on the results of these blood tests. No matter what dosage of COUMADIN you take, make sure you always take the dosage your healthcare provider prescribes for you, and make sure you always take the prescribed dosage every day.

**WHY ARE REGULAR BLOOD TESTS SO IMPORTANT?**

**Q** What is the blood test and what is it used for?

**A** The blood test is called a PT/INR test. PT/INR stands for Prothrombin Time and International Normalized Ratio. These tests are used to see how quickly your blood clots and whether you’re getting the right amount of COUMADIN. Only a small amount of blood is taken each time.

The number tells your healthcare provider if COUMADIN (Warfarin Sodium) is helping you maintain the appropriate PT/INR level for your condition. Your healthcare provider will tell you what PT/INR level is right for you.

**Q** How often do I have my blood tested?

**A** Your healthcare provider will determine how often you will need blood tests. Your COUMADIN (Warfarin Sodium) dosage may be carefully adjusted (raised or lowered) to keep your PT/INR level right for your condition. The results are usually available the same day. When you get these results, ask your healthcare provider if you will need to change your dosage of COUMADIN.

When you have your blood tested, be sure to:

- Go to the laboratory on the date and time scheduled.
- Go to the same laboratory each time, because the results you get may differ from one laboratory to another.
- Ask your healthcare provider what dose you should take that day, and each day until you have your next blood test.
- If your dose is changed, make a note of your new dose on your calendar or in a place easily visible to you.

Please see Indications and Important Safety Information on pages 14-15 and “What is the most important information I should know about COUMADIN?” for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
particular medicines. This is very important because your healthcare provider may need to adjust the dosage of these medications as well as COUMADIN.

Do not take other drugs that contain warfarin. Warfarin is the active ingredient in COUMADIN. If you take other warfarin medication while taking COUMADIN (Warfarin Sodium), you may get an overdose of warfarin. Remember, COUMADIN tablets look different from other warfarin tablets, and have different markings on them, so it is possible to take both by mistake.

**WHAT ARE SOME THINGS THAT CAN MAKE MY PT/INR RESULTS CHANGE?**

Many over-the-counter or prescription drugs, vitamins and herbal supplements, certain foods, and certain medical conditions can interact with COUMADIN (Warfarin Sodium) and change your PT/INR. (See "What is the most important information I should know about COUMADIN?" on pages 3-4)

For a list of possible interactions with COUMADIN, see the full Prescribing Information (written for healthcare providers). In addition, you should discuss your particular medicines, herbal supplements, diet, and medical conditions with your healthcare provider.

**Prescription drugs**

Many different medications, used to treat many different conditions, may affect your body’s response to COUMADIN. They may increase or decrease your PT/INR level. Some common prescription medications may interact with COUMADIN (Warfarin Sodium). Please see the full Prescribing Information (written for healthcare providers), and speak with your healthcare provider about this information and your
Vitamins may also affect how your body responds to COUMADIN, and change your PT/INR level. Too much vitamin K, in particular, can lower the blood-thinning effect of COUMADIN. You should tell your healthcare provider if you are taking any vitamin supplement, including a vitamin K supplement.

**What other medical procedures and conditions should my healthcare provider know about?**

**A**

Before starting COUMADIN (Warfarin Sodium), tell your healthcare provider about all of your health conditions.

If you are having surgery, including dental surgery, tell the healthcare provider performing the procedure that you are taking COUMADIN. You may be told by your healthcare provider to stop taking COUMADIN before your procedure.

In addition, you may need to have a blood test before having your procedure. For information about checking your PT/INR, see “Why are regular blood tests so important?” on page 9.
WHAT IF…?

Q I stop taking COUMADIN—how long will the blood-thinning effects of COUMADIN (Warfarin Sodium) continue?

A If your healthcare provider stops your COUMADIN therapy, the anticlotting effect may last for about 2 to 5 more days.

Q I want to travel—is there anything special I should do?

A Speak with your healthcare provider first. He or she may ask you to take a PT/INR test before your trip, or arrange for you to take the test while you’re away.

Two things to keep in mind:

■ While traveling, be mindful of taking your COUMADIN at the same time every day. It is very important to maintain a consistent amount of vitamin K in your diet. You should avoid drastic changes in your dietary habits.

■ Be sure to take enough COUMADIN (Warfarin Sodium) for your entire trip. You should also carry your medications with you at all times; do not put them in checked baggage or leave them in the car.

Q What if I cut myself or I start bleeding?

A Because COUMADIN (Warfarin Sodium) affects clotting, it may take longer for bleeding to stop if you are cut or injured.

■ If your cut is small, apply constant pressure until the bleeding stops. This may take up to 10 minutes. If the bleeding doesn’t stop, keep applying pressure and seek medical attention.

■ If your cut is large, apply constant pressure and get help immediately by going to the emergency room or calling for medical help.

To avoid cutting yourself while shaving:

■ Rather than using a razor with a razor blade, use an electric razor or hair-removing cream.

To reduce gum bleeding while brushing your teeth:

■ Use a soft toothbrush, and brush and floss gently.

Please see Indications and Important Safety Information on pages 14-15 and “What is the most important information I should know about COUMADIN?” for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
DO I HAVE TO PAY ATTENTION TO THE VITAMIN K IN MY DIET?

Q Can the foods I eat affect my response to COUMADIN (Warfarin Sodium)?

A The foods that contain vitamin K can interfere with the blood-thinning effects of COUMADIN. It is very important to maintain a consistent amount of vitamin K in your diet. Avoid drastic changes in your dietary habits. For instance, eating large amounts of green leafy vegetables, when you normally do not, can increase the amount of vitamin K in your system.

Q Should I stay on the same general diet every day?

A Do not make any major changes to your diet without speaking with your healthcare provider first. If you change your eating habits, your healthcare provider may give you a blood test more frequently to see if your COUMADIN (Warfarin Sodium) is working effectively.

Q How can I tell how much vitamin K is in the food I eat?

A Many foods have low amounts of vitamin K, including beverages, dairy products, bread, cereal, and meat. Leafy green vegetables, such as kale, parsley, spinach, and turnip greens, as well as broccoli and brussels sprouts, contain large amounts of vitamin K. Speak with your healthcare provider if you have any questions about the vitamin K content in your food.

Q How much alcohol may I have?

A Drinking alcohol can change your PT/INR. Be sure to speak with your healthcare provider about the amount of alcohol you consume.

Please see Indications and Important Safety Information on pages 14-15 and “What is the most important information I should know about COUMADIN?” for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
INDICATIONS:

- COUMADIN® (Warfarin Sodium) 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.

IMPORTANT SAFETY INFORMATION:

- COUMADIN can cause serious and life-threatening bleeding. Bleeding is more likely to occur when you first start taking COUMADIN and with a higher dose.
- Factors that can increase your risk of bleeding while on COUMADIN (Warfarin Sodium) therapy include being 65 years of age or older, an INR greater than 4, highly variable INRs, history of bleeding involving the stomach or intestine, high blood pressure, certain diseases of the brain, heart or kidney, anemia, cancer, physical injury, taking other drugs, and a long duration of therapy.
- 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.
- Tell your healthcare provider right away if you have any signs or symptoms of bleeding problems such as the following: pain, swelling or discomfort, headache, dizziness, or weakness, unusual bruising, nosebleeds, bleeding of gums, bleeding from cuts that take a long time to stop, menstrual flow or vaginal bleeding that is heavier than normal, pink or brown urine, red or black stools, coughing up blood, or vomiting blood or material that looks like coffee grinds.

More About COUMADIN

- Do not take COUMADIN if 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.
- Speak to your healthcare provider before breast-feeding while taking COUMADIN (Warfarin Sodium).
- Tell your healthcare provider about all the medical conditions you may have, including recent or planned surgeries or medical or dental procedures.
- Unsupervised patients with declining mental function due to aging or mental illness, and patients with alcoholism or increased risk of bleeding should not take COUMADIN (Warfarin Sodium).
- Death of skin tissue (skin necrosis or gangrene) is a serious side effect of 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.
- Call your healthcare provider right away if you have pain in your toes and they look purple or dark in color. You may be experiencing a serious condition known as purple toes syndrome.

(CONTINUED)
IMPORTANT SAFETY INFORMATION
(CONTINUED):

- Many factors alone or together such as changes in diet and medicines, including herbal supplements, may affect your response to COUMADIN (Warfarin Sodium). Tell your healthcare provider about your diet, all prescription and non-prescription medicines, vitamins, and herbal products you are taking or plan to take. Speak with your healthcare provider before starting, changing, or stopping any of these products. Many drugs, including aspirin and other pain medicines, may interact with COUMADIN.
- Eat a normal balanced diet. Do not make changes in your diet, such as eating large amounts of leafy green vegetables, which contain vitamin K without first talking to your healthcare provider.
- Avoid alcohol consumption, cranberry juice, and cranberry products while taking COUMADIN.
- Tell your doctor if you have any illness such as diarrhea, infection or fever.
- Be aware that COUMADIN and generic warfarin tablets represent the same medication and should not be taken together, as overdosage may result.
- If you take too much or miss a dose of COUMADIN, call your healthcare provider. Take the missed dose as soon as possible on the same day. Do not take a double dose of COUMADIN (Warfarin Sodium) the next day to make up for a missed dose.
- If you have any other questions about COUMADIN and your condition, contact your healthcare provider.

Please see Indications and Important Safety Information on pages 14-15 and “What is the most important information I should know about COUMADIN?” for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
**PATIENT DOSENG CALENDAR**

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# PATIENT DOSING CALENDAR

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**NOTES:**

Please see Indications and Important Safety Information on pages 14-15 and “What is the most important information I should know about COUMADIN?” for information on the boxed WARNING regarding bleeding risk in the Medication Guide and full Prescribing Information at the end of this booklet.
# PATIENT DOSING CALENDAR

**Month:**

<table>
<thead>
<tr>
<th>Date/Day</th>
<th>Daily Dose of COUMADIN® (Warfarin Sodium)</th>
<th>Time Dose Taken</th>
<th>PT/INR</th>
<th>Next Appointment</th>
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**NOTES:**

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Crystalline warfarin sodium occurs as a white, odorless, crystalline powder, is dissolved by light and is very soluble in water; freely soluble in alcohol; very slightly soluble in chloroform and in ether.

COUMADIN Tablets for oral use also contain:
- All strengths: Lactose, starch and magnesium stearate
- 1 mg: D&C Red No. 4, Barium Lake
- 2 mg: FD&C Blue No. 2 Aluminum Lake and FD&C Red No. 40 Aluminum Lake
- 2.5 mg: FD&C Yellow No. 10 Aluminum Lake and FD&C Blue No. 1 Aluminum Lake
- 3 mg: FD&C Yellow No. 6 Aluminum Lake and FD&C Blue No. 2 Aluminum Lake and FD&C Red No. 40 Aluminum Lake
- 4 mg: FD&C Blue No. 1 Aluminum Lake
- 5 mg: FD&C Yellow No. 6 Aluminum Lake
- 6 mg: FD&C Yellow No. 6 Aluminum Lake and FD&C Blue No. 1 Aluminum Lake
- 7.5 mg: FD&C Yellow No. 10 Aluminum Lake and FD&C Blue No. 6 Aluminum Lake
- 10 mg: Dye Free

COUMADIN for injection is supplied as a sterile, lyophilized powder, which, after reconstitution with 2.7 mL sterile Water for Injection, contains:
- Warfarin Sodium 2 mg/mL
- Sodium Phosphate, Dibasic, Hepatidrate 4.08 mg/mL
- Sodium Phosphate, Monobasic, Monohydrate 0.194 mg/mL
- Sodium Chloride 0.1 mg/mL
- Mannitol 38.0 mg/mL
- Sodium Hydroxide, as needed for pH adjustment to 8.1 to 8.3

CLINICAL PHARMACOLOGY
COUMADIN and other coumarin anticoagulants act by inhibiting the synthesis of vitamin K dependent clotting factors, which include Factors II, VII, IX and X, and the antihemophilic globulin and protein C and S. Half-lives of these clotting factors are as follows: Factor II ~ 60 hours; Factor VII ~ 4 hours; Factor IX ~ 24 hours; and X ~ 48 to 72 hours. The half-life of proteins C and S are approximately 8 hours and 30 hours, respectively.

An anticoagulant effect generally occurs within 24 hours after drug administration. However, peak anticoagulant effect may be delayed 72 to 96 hours. The duration of action of a single dose of racemic warfarin is 2 to 5 days. The effects of COUMADIN may become more pronounced as effects of daily maintenance doses overlap. Anticoagulants have no direct effect on an established thrombus, nor do they reverse extension of ischemic tissue damage. However, once a thrombus has occurred, the goal of antithrombotic treatment is to prevent further extension of the clot and prevent secondary thromboembolic complications which may result in serious and possibly fatal sequelae.

Pharmacokinetics: COUMADIN is a racemic mixture of the R- and S-enantiomers. The S-enantiomer exhibits 2 to 5 times more anticoagulant activity than the R-enantiomer in humans, but generally has a more rapid clearance. Absorption: COUMADIN is essentially completely absorbed after oral administration with peak concentration generally attained within the first 4 hours.

Distribution: There are no differences in the apparent volumes of distribution after intravenous and oral administration of single doses of warfarin solution. Warfarin distributes into a relatively small apparent volume of distribution, which modulates the in vivo anticoagulant activity of warfarin.

Toxicity: The elimination of warfarin is almost entirely by metabolism. COUMADIN is stereospecifically metabolized by hepatic microsomal enzymes (cytochrome P-450) to inactive hydroxylated metabolites (predominantly R-warfarin and S-warfarin) and reduced metabolites (warfarin alcohols). The warfarin alcohols have minimal anticoagulant activity. The metabolites are principally excreted into the urine; and to a lesser extent into the bile. The metabolites of warfarin that have been identified include dehydrowarfarin, two diastereomers of R-oxo-7-warfarin, 4-, 6-, 7- and 10-hydroxywarfarin, and 6'-, 7-, 8- and 10-hydroxywarfarin. The cytochrome P-450 isozymes involved in the metabolism of warfarin that have been identified include CYP2C9, CYP2C19, CYP2C9-2, CYP2C19-1A2, and CYP4A11. 3.64. Warfarin is likely to be the principal form of human liver P-450 which metabolizes the in vivo anticoagulant activity of warfarin.

The S-enantiomer of warfarin is mainly metabolized to 7-hydroxycoumarin by CYP2C9, a polymorphic enzyme. The variant alleles CYP2C9*2 and CYP2C9*3 result in decreased in vitro CYP2C9 enzymatic 7-hydroxylation of S-warfarin. The frequencies of these alleles in Caucasians are approximately 11% and 7% for CYP2C9*2 and CYP2C9*3, respectively. Patients with one or more of these variant CYP2C9 alleles have decreased S-warfarin clearance (Table 1).
Inadequate laboratory facilities.

...onset of minor bleeder episodes was higher in the combined therapy group. The primary endpoint was a composite of death, nonfatal rebleeding, or thromboembolic stroke. The mean duration of observation was approximately 4 years. The results for WARIS II are included in the following table.6

In a prospective, randomized, open-label, positive-controlled study9

Mechanical and Bioprosthetic Heart Valves:

COUMADIN is indicated to reduce the risk of death, recurrent myocardial infarction, and thromboembolic events...
Potential drug interactions with COUMADIN are listed below by drug class and by specific drugs.

### Classes of Drugs

- **Antithyroid Drugs†**
  - Amiodarone HCl
  - Aminosalicylic acid
  - Allopurinol
  - Azathioprine
  - Barbiturates
  - Barbiturates (oral)
  - Beta-Adrenergic Blockers
  - Betaxolol
  - Bisacodyl
  - Biperiden
  - Bromocriptine
  - Bromocriptine mesylate
  - Butabarbital
  - Butylamine derivatives
  - Caffeine derivatives
  - Calcitonin
  - Calcitriol
  - Calcitonin (oral)
  - Calcitonin (subcutaneous)
  - Camptothecin
  - Carbamazepine
  - Carbamazepine, extended-release
  - Carbamazepine, immediate-release
  - Carbamazepine, sustained-release
  - Carbamazepine, sustained-release (extended-release)
  - Carbamazepine, controlled-release
  - Carbamazepine, extended-release (controlled-release)
  - Carbamazepine, extended-release (controlled-release)
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COUMADIN® (warfarin sodium)

Intramuscular (IM) injections of concomitant medications should be confined to the upper extremities which permits easy access for manual compression, inspections for bleeding and use of pressure bandages.

Caution should be observed when COUMADIN (or warfarin) is administered concomitantly with nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, to be certain that no change in anticoagulation dosage is required. In addition to warfarin, antiplatelet agents (such as aspirin and clopidogrel), can inhibit platelet aggregation, and can cause gastrointestinal bleeding, peptic ulceration and/or perforation.

Information for Patients: The objective of anticoagulant therapy is to decrease the clotting ability of the blood so that thrombosis can be prevented. Generally, therapeutic levels of warfarin sodium in the plasma, when maintained, can inhibit platelet aggregation, and can cause gastrointestinal bleeding, peptic ulceration and/or perforation.

Do not take or discontinue any other medication, including salicylates (eg, aspirin and topical analgesics), other over-the-counter medications, and herbal (botanical) products except on advice of the physician. Avoid alcohol consumption and use of other substances that can affect anticoagulation (eg, garlic, tea, ginseng, gingko) and take care in situations where bleeding could be a problem (eg, dental procedures, surgeries, trauma, pregnancy).

Geriatric Use: Consideration of geriatric use is important determinants of warfarin dose. Patients with CYP2C9 *1/*3, *2/*2, *2/*3, and *3/*3 may require more

Clinical pharmacokinetic information, when available, can assist in selecting the starting dose. Table 1 describes the range of stable maintenance doses observed in patients with different combinations of VKORC1 and CYP2C9 genotypes. Consider these ranges in choosing the initial dose.

In all patients, subsequent dosage adjustments must be made based on the results of PT/INR determinations.

Table 5: Range of Expected Therapeutic Warfarin Doses Based on CYP2C9 and VKORC1 Genotypes

<table>
<thead>
<tr>
<th>VKORC1</th>
<th>CYP2C9</th>
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<tbody>
<tr>
<td></td>
<td>*1/*1</td>
</tr>
<tr>
<td>GG</td>
<td>5-7 mg</td>
</tr>
<tr>
<td>AG</td>
<td>5-7 mg</td>
</tr>
<tr>
<td>AA</td>
<td>3-4 mg</td>
</tr>
</tbody>
</table>

DOSAGE AND ADMINISTRATION

The dose of COUMADIN must be individualized for each patient according to the particular patient’s PT/INR response to the drug. The dosage should be adjusted based upon the patient’s PT/INR.

The best available information supports the following recommendations for dosing of COUMADIN.

Venous Thrombophlebitis: The risk of serious venous deep venous thrombosis (DVT) or pulmonary embolism (PE) for patients with a first episode of DVT or PE secondary to a transient (reversible) risk factor, treatment with warfarin for 3 months is recommended. For patients with a first episode of idiopathic DVT or PE, treatment for at least 6 months is recommended. For patients with a first episode of DVT or PE who have documented antiphospholipid antibodies, venous thromboembolic disease, or a prothrombotic condition, initial doses of warfarin should be somewhat higher to achieve the therapeutic INR range. For patients with a first episode of DVT or PE who have documented deficiency of antithrombin, deficiency of Protein C or Protein S, or the Factor V Leiden or prothrombin 20210 gene mutation, homocysteinemia, or high Factor VII levels (>50th percentile of normal), treatment for 6 to 12 months is recommended and indefinite therapy is suggested for idiopathic thrombosis. The risk-benefit should be reassessed periodically in patients who receive indefinite anticoagulant treatment. The dosage of warfarin should be adjusted to maintain a target INR of 2.5 (INR range, 2.0-3.0) for all treatment durations. These recommendations are supported by the American College of Chest Physicians’ (7th ACCP) guidelines.

Arterial Thrombosis: Five clinical trials evaluated the effects of warfarin in patients with non-valvular atrial fibrillation who are at high risk of stroke. These trials included patients with a past history of stroke or TIAs, and patients with non-valvular atrial fibrillation and other risk factors. The 7th ACCP guidelines recommend warfarin for these patients, with a target INR of 2.0 to 2.5, to reduce the risk of stroke.

Oral anticoagulation with warfarin is recommended in patients with persistent or paroxysmal AF (paroxysmal AF, intermittent AF) at high risk of stroke (ie, having any of the following features: prior ischemic stroke, transient ischemic attack, or atrial fibrillation with heart failure). The 7th ACCP guidelines recommend that in the low INR range of 1.5 to 1.9, anticoagulation with warfarin is not recommended due to the risk of bleeding complications with atrial fibrillation and vascular heart disease. Similar data from clinical studies in vascular atrial fibrillation patients are not available. The trials in non-valvular atrial fibrillation support the 7th ACCP recommendation that an INR of 2.0 to 2.5 be used to guide COUMADIN therapy.

Post-Myocardial Infarction: The results of the WARIS II study and 7th ACCP guidelines suggest that in most patients, regardless of whether the patient has persistent or paroxysmal AF, an INR of 2.5 (range, 2.0-3.0) is recommended with oral anticoagulation in order to promote thrombus lysis and synergize with oral anti-platelet therapy (ASA). The 7th ACCP guidelines recommend an INR of 2.0 to 3.0 for patients with persistent AF who are in atrial flutter or atrial fibrillation (AF) and for patients with paroxysmal AF who are in atrial flutter or AF at the time of stroke.

In patients with AF and prosthetic heart valves, warfarin therapy is recommended and the target INR may be increased and aspirin added depending on valve type and position, and on patient factors.

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warfarin products are interchanged with warfarin sodium tablets, USP, as well as whenever other medications are initiated, discontinued, or taken irregularly (see PRECAUTIONS). Safety and efficacy of warfarin therapy can be improved by increasing the quality of laboratory control. Reports suggest that in usual care monitoring, patients are in therapeutic range only 23% to 64% of the time. Time in therapeutic range is significantly greater (56%-93%) in patients managed by anticoagulation clinics, among self-testing and self-monitoring patients, and in patients managed with the help of computer programs. Self-testing patients had fewer bleeding events than patients in usual care.

Treatment During Dentistry and Surgery: The management of patients who undergo dental and surgical procedures requires close liaison between attending physicians, surgeons, and dentists. Prior PT/INR determination is recommended just prior to any dental or surgical procedure. In patients undergoing minimal invasive procedures who must be anticoagulated prior to, during, or immediately following these procedures, adjusting the dosage of COUMADIN® to maintain the PT/INR at the low end of the therapeutic range may safely allow for continued anticoagulation. The operative site should be sufficiently limited and accessible to permit the effective use of local procedures for hemostasis. Under these conditions, dental and minor surgical procedures may be performed without undue risk of hemorrhage. Some dental or surgical procedures may necessitate the interruption of COUMADIN® therapy. When discontinuing COUMADIN® even for a short period of time, the benefits and risks should be strongly considered.

Conversion From Heparin Therapy: Since the anticoagulant effect of COUMADIN is delayed, heparin is preferred initially for rapid anticoagulation. Conversion to COUMADIN® may begin concomitantly with heparin therapy or may be delayed 3 to 6 days. To ensure continuous anticoagulation, it is advisable to continue full-dose heparin therapy and that COUMADIN® therapy be overlapped with heparin for 4 to 5 days, until COUMADIN® has produced the desired PT/INR or prothrombin activity, heparin may be discontinued.

COUMADIN® may increase the activated partial thromboplastin time (APTT) test, even in the absence of heparin. A severe elevation (30-60 seconds) in activated partial thromboplastin time (APTT) with a PT/INR in the desired range has been identified as an indication of increased risk of postoperative hemorrhage. During initial therapy with COUMADIN®, the interference with heparin anticoagulation is of minimal clinical significance.

As heparin affects the PT/INR, patients receiving both heparin and COUMADIN® should have blood for PT/INR determination drawn at least:
• 5 hours after the last IV bolus dose of heparin, or
• 4 hours after cessation of a continuous IV infusion of heparin, or
• 24 hours after the last subcutaneous heparin injection.

HOW SUPPLIED
Tablets: For oral use, single scored with one face imprinted numerically with 1, 2, 2-1/2, 3, 4, 5, 6, 7-1/2 or 10 superimposed and inscribed with “COUMADIN®” and with the opposite face plain. COUMADIN® is available in bottles and Hospital Unit-Dose Blister Packages with potencies and colors as follows:

<table>
<thead>
<tr>
<th>Table</th>
<th>Potency</th>
<th>Color</th>
<th>NDC Code</th>
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<tbody>
<tr>
<td>1 mg pink</td>
<td>NDC 0056-0168-70</td>
<td>NDC 0056-0168-60</td>
<td>NDC 0056-0168-75</td>
</tr>
<tr>
<td>2 mg lavender</td>
<td>NDC 0056-0170-70</td>
<td>NDC 0056-0170-60</td>
<td>NDC 0056-0170-75</td>
</tr>
<tr>
<td>2-1/2 mg green</td>
<td>NDC 0056-0176-70</td>
<td>NDC 0056-0176-60</td>
<td>NDC 0056-0176-75</td>
</tr>
<tr>
<td>3 mg tan</td>
<td>NDC 0056-0186-70</td>
<td>NDC 0056-0186-60</td>
<td>NDC 0056-0186-75</td>
</tr>
<tr>
<td>4 mg blue</td>
<td>NDC 0056-0186-70</td>
<td>NDC 0056-0186-60</td>
<td>NDC 0056-0186-75</td>
</tr>
<tr>
<td>5 mg peach</td>
<td>NDC 0056-0172-70</td>
<td>NDC 0056-0172-60</td>
<td>NDC 0056-0172-75</td>
</tr>
<tr>
<td>6 mg tan</td>
<td>NDC 0056-0189-70</td>
<td>NDC 0056-0189-60</td>
<td>NDC 0056-0189-75</td>
</tr>
<tr>
<td>7-1/2 mg yellow</td>
<td>NDC 0056-0179-70</td>
<td>NDC 0056-0179-60</td>
<td>NDC 0056-0179-75</td>
</tr>
<tr>
<td>10 mg white (Dye Free)</td>
<td>NDC 0056-0174-70</td>
<td>NDC 0056-0174-60</td>
<td>NDC 0056-0174-75</td>
</tr>
</tbody>
</table>

Protect from light. Store at controlled room temperature (59°-86°F, 15°-30°C). Dispense in a tight, light-resistant container as defined in the USP.

Hospital Unit-Dose Blister Packages are to be stored in carton until contents have been used.

Injection: Available for intravenous use only. Not recommended for intramuscular administration. Reconstitute with 2.7 ml of sterile Water for Injection to yield 2 mg/mL. Net contents 5.4 mg lyophilized powder. Maximum 2.5 mL.

5 mg vial (box of 6) NDC 0050-0324-35


After reconstitution, store at controlled room temperature (59°-86°F, 15°-30°C) and use within 4 hours. Do not refrigerate. Discard any unused solution.

REFERENCES
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 should I tell my healthcare provider before starting COUMADIN?

• You and your healthcare provider should talk about COUMADIN when you start taking it and at regular checkups.

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.

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.

• Tell your healthcare provider right away if you take too much COUMADIN.

• Tell 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 healthcare provider.

Rx only

COUMADIN is distributed by:

Bristol-Myers Squibb
Princeton, New Jersey 08543 USA

COUMADIN® (warfarin sodium) is a registered trademark of Bristol-Myers Squibb Pharma Company.

COUMADIN (Warfarin Sodium), the COUMADIN color logo, COLORS OF COUMADIN, and the color and configuration of COUMADIN tablets are trademarks of Bristol-Myers Squibb Pharma Company.

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