MEDICATION GUIDE
Warfarin (WAR-far-in) **Sodium** (SO-dee-um) **Tablets**

The 7.5 mg tablets contain FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

What is the most important information I should know about warfarin sodium tablets?
Warfarin sodium tablets can cause bleeding which can be serious and sometimes lead to death. This is because warfarin sodium tablets are 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 warfarin sodium tablets 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
    - non-steroidal anti-inflammatory drugs (NSAIDs)
  - take warfarin sodium for a long time. Warfarin sodium is the active ingredient in warfarin sodium tablets.

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 listed above.
Many other medicines can interact with warfarin sodium tablets and affect the dose you need or increase warfarin sodium tablets side effects. Do not change or stop any of your medicines or start any new medicines before you talk to your healthcare provider.
Do not take other medicines that contain warfarin sodium while taking warfarin sodium tablets.

- **Get your regular blood test to check for your response to warfarin sodium tablets.** This blood test is called an INR test. The INR test checks to see how fast your blood clots. Your healthcare provider will decide what INR numbers are best for you. Your dose of warfarin sodium tablets will be adjusted to keep your 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

- **Some foods and beverages can interact with warfarin sodium tablets and affect your treatment and dose.**
  - Eat a normal, balanced diet. Talk to your healthcare provider 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 warfarin sodium tablets.
- Always tell all of your healthcare providers that you take warfarin sodium tablets.
- Wear or carry information that you take warfarin sodium tablets.

See "What are the possible side effects of warfarin sodium tablets?" for more information about side effects.

What are warfarin sodium tablets?

Warfarin sodium tablets are 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.

Who should not take warfarin sodium tablets?

Do not take warfarin sodium tablets if:

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

Before taking warfarin sodium tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have bleeding problems
- fall often
- have liver problems
- have kidney problems or are undergoing dialysis
- have high blood pressure
- have a heart problem called congestive heart failure
- have diabetes
- plan to have any surgery or a dental procedure
- are pregnant or plan to become pregnant. See " **Who should not take warfarin sodium tablets?**"
  - Your healthcare provider will do a pregnancy test before you start treatment with warfarin sodium tablets. Females who can become pregnant should use effective birth control during treatment, and for at least 1 month after the last dose of warfarin sodium tablets.
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are breastfeeding. You and your healthcare provider should decide if you will take warfarin sodium tablets and breastfeed. Check your baby for bruising or bleeding if you take warfarin sodium tablets and breastfeed.

Tell all of your healthcare providers and dentists that you are taking warfarin sodium tablets. They should talk to the healthcare provider who prescribed warfarin sodium tablets for you before you have **any** surgery or dental procedure. Your warfarin sodium tablets may need to be stopped for a short time or you may need your dose adjusted.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some of your other medicines may affect the way warfarin sodium tablets work. Certain medicines may increase your risk of bleeding. See "**What is the most important information I should know about warfarin sodium tablets?**"

How should I take warfarin sodium tablets?

- **Take warfarin sodium tablets exactly as prescribed.** Your healthcare provider will adjust your dose from time to time depending on your response to warfarin sodium tablets.
- **You must have regular blood tests and visits with your healthcare provider to monitor your condition.**
- **If you miss a dose of warfarin sodium tablets, call your healthcare provider.** Take the dose as soon as possible on the same day. **Do not** take a double dose of warfarin sodium tablets the next day to make up for a missed dose.
- Call your healthcare provider right away if you:
  - take too much warfarin sodium tablets
  - are sick with diarrhea, an infection, or have a fever
  - fall or injure yourself, especially if you hit your head. Your healthcare provider may need to check you.

What should I avoid while taking warfarin sodium tablets?

- Do not do any activity or sport that may cause a serious injury.

What are the possible side effects of warfarin sodium tablets?
Warfarin sodium tablets may cause serious side effects including:

- See " **What is the most important information I should know about warfarin sodium tablets?**"
- **Death of skin tissue (skin necrosis or gangrene).** This can happen soon after starting warfarin sodium tablets. 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.
- **Kidney problems.** Kidney injury may happen in people who take warfarin sodium tablets. Tell your healthcare provider right away if you develop blood in your urine. Your healthcare provider may do tests more often during treatment with warfarin sodium tablets 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 in color or dark in color.

These are not all of the side effects of warfarin sodium tablets. 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 warfarin sodium tablets?

- Store warfarin sodium tablets at 20° to 25°C (68° to 77°F).
- Keep warfarin sodium tablets in a tightly closed container.
- Keep warfarin sodium tablets out of the light.
- Follow your healthcare provider or pharmacist instructions about the right way to throw away outdated or unused warfarin sodium tablets.
- Females who are pregnant should not handle crushed or broken warfarin sodium tablets.

Keep warfarin sodium tablets and all medicines out of the reach of children.

General information about the safe and effective use of warfarin sodium tablets.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use warfarin sodium tablets for a condition for which they were not prescribed. Do not give warfarin sodium tablets to other people, even if they have the same symptoms that you have. They may harm them. You can ask your healthcare provider or pharmacist for information about warfarin sodium tablets that is written for health professionals.

What are the ingredients in warfarin sodium tablets?
Active ingredient: warfarin sodium
Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. The 1 mg also contains FD&C red no. 40. The 2 mg also contains FD&C blue no. 2 aluminum lake and FD&C red no. 40 aluminum lake. The 2.5 mg also contains D&C yellow no. 10 aluminum lake and FD&C blue no. 1 aluminum lake. The 3 mg also contains FD&C yellow no. 6 aluminum lake, FD&C blue no. 2 aluminum lake, FD&C red no. 40 aluminum lake, and D&C yellow no. 10 aluminum lake. The 4 mg also contains FD&C blue no. 1 aluminum lake and FD&C blue no. 2 aluminum lake. The 5 mg also contains FD&C yellow no. 6 aluminum lake, FD&C red no. 40 aluminum lake and D&C yellow no. 10 aluminum lake. The 6 mg also contains D&C yellow no. 10 aluminum lake and FD&C blue no. 1 aluminum lake. The 7.5 mg also contains FD&C yellow no. 5 (tartrazine) aluminum lake and FD&C red no. 40 aluminum lake.
For more information, go to www.tevagenerics.com or call 1-888-838-2872.

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