

INFORMATION FOR THE PATIENT

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APO-WARFARIN

Warfarin Sodium Tablets USP

Please read this leaflet before you start taking Apo-Warfarin (warfarin sodium). Each time you renew your prescription, read the leaflet that comes with your medicine, just in case any information has changed. Remember, this leaflet does not take the place of talking to your health care provider (such as your doctor, nurse, or pharmacist). You and your health care provider should discuss Apo-Warfarin when you start taking your medication and at regular checkups.

1. What is Apo-Warfarin?

- Apo-Warfarin is an anticoagulant drug. "Anti" means against, and "coagulant" refers to blood clotting. An anticoagulant helps reduce clots from forming in the blood.
- Apo-Warfarin is a narrow therapeutic index drug, which means that there is a narrow margin between too much and too little of the drug. Too much drug may cause you to bleed more. Too little drug may let a harmful clot form.

2. How does Apo-Warfarin work?

- Apo-Warfarin partially blocks the re-use of vitamin K in your liver. Vitamin K is needed to make clotting factors that help the blood to clot and prevent bleeding. Vitamin K is found naturally in foods such as leafy, green vegetables and certain vegetable oils.
- Apo-Warfarin begins to reduce blood clotting within 24 hours after taking the drug. The full effect may take 72 to 96 hours to occur. The anti-clotting effects of a single dose of Apo-Warfarin last 2 to 5 days, but it is important for you to take your dose every day.

3. What is the most important information I should know when taking Apo-Warfarin?

- Like all prescription drugs, Apo-Warfarin may cause side effects. The most common side effect of Apo-Warfarin is bleeding, which may be serious. However, the risk of serious bleeding is low when the effect of Apo-Warfarin is within a range that is right for your specific medical condition. Notify your health care provider right away of any unusual bleeding or if signs or symptoms of bleeding occur (see Question 5).
- Do not take Apo-Warfarin during pregnancy. Use effective measures to avoid pregnancy while taking Apo-Warfarin.
- The dose of Apo-Warfarin may be different for each patient. For example, older patients (age 60 years of age or older) appear to have a greater-than-expected response to Apo-Warfarin so that as patient age increases, a lower dose of Apo-Warfarin may be needed. Your health care provider will decide what dose is best for you. This dose may change from time to time.
- To decide on the dosage of Apo-Warfarin you need, your health care provider will take a small amount of your blood to find out your prothrombin time, protime, or PT, for short. Protimes are often recorded as an INR (International Normalized Ratio), a standard way of reporting protimes.
- PT/INR tests are very important. They help your health care provider see how fast your blood is clotting and whether your dosage of Apo-Warfarin should change.
- When you start taking Apo-Warfarin, you may have PT/INR tests every day for a few days, then perhaps one time every week. These PT/INR tests and regular visits to a health care provider are very important for the success of therapy with Apo-Warfarin. PT/INR tests will be needed at periodic intervals (such as one time per month) throughout your course of therapy to keep your PT/INR in the best range for your medical condition. Discuss with your health care provider the range that is right for you.
- Eat a normal, balanced diet maintaining a consistent level of green, leafy vegetables that contain high amounts of Vitamin K, since the amount of vitamin K in your daily diet may affect Apo-Warfarin therapy.
- Report any illness, such as throwing up (vomiting), loose or runny stools (diarrhea), an infection or fever, to your health care provider.
- Tell anyone giving you medical or dental care that you are taking Apo-Warfarin.
- Carry identification stating that you are taking Apo-Warfarin.

4. How should I take Apo-Warfarin?

- Take Apo-Warfarin exactly the way your health care provider tells you and take it at the same time every day. You can take Apo-Warfarin either with food or on an empty stomach. Your dosage may change from time to time depending on your response to Apo-Warfarin.
- If you miss a dose of Apo-Warfarin, notify your health care provider right away. Take the dose as soon as possible on the same day, but do not take a double dose of Apo-Warfarin the next day to make up for a missed dose.

5. What are the possible side effects of Apo-Warfarin?

Your health care provider can tell you about possible side effects of Apo-Warfarin, which include bleeding and allergic reactions. Please contact your health care provider right away if you experience signs or symptoms of bleeding or allergic reactions.

To lower the risk of bleeding, your PT/INR should be kept within a range that is right for you. Signs or symptoms of bleeding include:

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

Serious, but rare, side effects of Apo-Warfarin 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 health care provider for further information on these side effects.

Hypersensitivity/allergic reactions are reported infrequently. Signs or symptoms of these reactions may range from mild reactions (rash, itching, hives) to more severe reactions (trouble breathing, throat tightening or constriction, facial swelling, swollen lips or tongue, sudden low blood pressure).

6. What should I avoid while taking Apo-Warfarin?

- Do not start, stop, or change any medicine except on advice of your health care provider. Apo-Warfarin interacts with many different drugs, including aspirin and aspirin-containing ointments and skin creams. Tell your health care provider about any prescription and non-prescription (over-the-counter) drugs that you are taking including occasional use of headache medications.
- Do not make drastic changes in your diet, such as eating large amounts of green, leafy vegetables. The amount of vitamin K in your daily diet may affect therapy with Apo-Warfarin.
- Do not attempt to change your weight by dieting, without first checking with your health care provider.
- Do not participate in any activity or sport that may result in serious injury.
- Avoid alcohol consumption.
- Avoid cutting yourself.

7. What does Apo-Warfarin look like?

Apo-Warfarin Tablets are available in many strengths, and each strength has a unique tablet color:

Tablet Strength	Tablet Color
1 mg	pink
2 mg	lavender
2 1/2 mg	green
3 mg	tan
4 mg	blue
5 mg	peach
10 mg	white (Dye free)

Each round, single-scored tablet is imprinted on one side with the word "WAR" and the numeric strength of the tablet. The other side of the tablet is imprinted with the name "APO".

Be sure to check that the tablet shows "APO", and "WAR" and the right numeric strength before you take it.



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APOTEX INC.
CANADA'S PHARMACEUTICAL COMPANY