APO-WARFARIN

Warfarin Sodium (1mg, 2mg, 5mg)

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What Apo-Warfarin is used for

Apo-warfarin helps to prevent blood from excessive clotting or forming harmful clots. If excessive clotting is not treated, it can lead to serious health problems such as strokes or heart attacks.

How Apo-Warfarin works

Apo-Warfarin is an anticoagulant medication. "Anti" means against, and "coagulant" refers to blood clotting. An anticoagulant helps reduce clots from forming in the blood.

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.

Before you use Apo-Warfarin

- When you must not use it You should not use Apo-Warfarin if you are allergic to Warfarin Sodium, or any ingredients in this medication.

Pregnancy and lactation

Do not take Apo-Warfarin if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Warfarin if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

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 diabetes
- Drink alcohol or have problems with alcohol abuse
- Have any scheduled operations/surgeries, even minor.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medications might cause complications when taken together with Apo-Warfarin, for example:

- -Acetalminophen, allopurinol, aspirin, azithromycin, capecitabine, cefoxitin, clarithromycin, dextran, diclofenac (prolonged bleeding time)
- Atorvastatin, azathioprine, chlordiazepoxide, phenytoin, ranitidine, vitamin K (reduce the effect of Apo-Warfarin)
- Non Steroidal Anti Inflammatory Drugs (NSAIDs)

How to use Apo-Warfarin

- How much to use

The administration and dosage of Apowarfarin is individualized according to your respond to the medicine.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the

label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Apo-Warfarin for as long as your doctor recommends.

- <u>If you forget to use it</u>

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Warfarin.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Apo-Warfarin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Apo-Warfarin can cause side effects, although not everybody gets them.

Side effect might include hemorrhage (excessive bleeding) from any tissue or organ. The sign and symptom will vary according to where it happens. The complications may present as headache, chest/abdomen/joint/muscle pain, dizziness, weakness.

Other side effects include: pain, hypersensitivity, fever, headache, dizziness, cold intolerance, nausea vomiting, rash.

More serious side effects would include:

- Some abnormalities in your breathing pathway (tracheal or tracheobronchial calcification) with prolonged treatment with this medication.
- Skin necrosis (skin tissue death)

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <u>portal.bpfk.gov.my</u> (Consumers → Reporting).

Storage and Disposal of Apo-Warfarin

- Storage

Keep out of the reach and sight of children.

Store below 25°C.

- <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Apo-Warfarin 1mg: Pink and round biconvex tablet scored and engraved 'WAR' over 1 on one side, 'APO' other side.

Apo-Warfarin 2mg: Lavender and round biconvex tablet scored and engraved 'WAR' over 2 on one side, 'APO' other side.

Apo-Warfarin 5mg: Peach and round biconvex tablet scored and engraved 'WAR' over 5 on one side, 'APO' other side.

- Ingredients

- Active ingredient Warfarin Sodium
- Inactive ingredients
 Lactose monohydrate,
 microcrystalline cellulose,
 magnesium stearate and starch.

Apo-Warfarin 1mg contains sunset yellow & D&C red #30.

Apo-Warfarin 2mg contains ferric ferrous oxide & D&C red #7.

Apo-Warfarin 5mg contains sunset yellow & D&C yellow #10.

- MAL numbers:

Apo-Warfarin 1mg: (MAL 20021394AZ)

Apo-Warfarin 2mg: (MAL 20021395AZ)

Apo-Warfarin 5mg: (MAL 20021396AZ)

Manufacturer

Apotex Inc.
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Product Registration Holder

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