

MEDICATION GUIDE
JANTOVEN® (JAN-to-ven) Tablets
(Warfarin Sodium Tablets, USP)

Read this Medication Guide before you start taking JANTOVEN (Warfarin Sodium Tablets, USP) and each time you get a refill. There may be new information. This Medication Guide 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 JANTOVEN when you start taking it and at regular checkups.

What is the most important information I should know about JANTOVEN?

JANTOVEN can cause bleeding which can be serious and sometimes lead to death. This is because JANTOVEN 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 JANTOVEN 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 JANTOVEN.

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 JANTOVEN and affect the dose you need or increase JANTOVEN 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 JANTOVEN.

- **Get your regular blood test to check for your response to JANTOVEN.** 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 JANTOVEN 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 JANTOVEN 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 JANTOVEN.
- Always tell all of your healthcare providers that you take JANTOVEN.
- Wear or carry information that you take JANTOVEN.

See “What are the possible side effects of JANTOVEN?” for more information about side effects.

What is JANTOVEN?

JANTOVEN is 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 JANTOVEN?

Do not take JANTOVEN if:

- **your chance of having bleeding problems is higher than the possible benefit of treatment.** Your healthcare provider will decide if JANTOVEN is right for you. Talk to your healthcare provider about all of your health conditions.

- **you are pregnant unless you have a mechanical heart valve.** JANTOVEN may cause birth defects, miscarriage, or death of your unborn baby.
- **you are allergic to warfarin or any of the other ingredients in JANTOVEN. See the end of this leaflet for a complete list of ingredients in JANTOVEN.**

What should I tell my healthcare provider before taking JANTOVEN?

Before you take JANTOVEN, tell your healthcare provider 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
- have any other medical conditions
- are pregnant or plan to become pregnant. See **“Who should not take JANTOVEN?”** Your healthcare provider will do a pregnancy test before you start treatment with JANTOVEN. Females who can become pregnant should use effective birth control during treatment, and for at least 1 month after the last dose of JANTOVEN.
- are breastfeeding. You and your healthcare provider should decide if you will take JANTOVEN and breastfeed. Check your baby for bruising or bleeding if you take JANTOVEN and breastfeed.

Tell all of your healthcare providers and dentists that you are taking JANTOVEN. They should talk to the healthcare provider who prescribed JANTOVEN for you before you have **any** surgery or dental procedure. Your JANTOVEN 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 JANTOVEN works. Certain medicines may increase your risk of bleeding. See **“What is the most important information I should know about JANTOVEN?”**

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take JANTOVEN?

- **Take JANTOVEN exactly as prescribed.** Your healthcare provider will adjust your dose from time to time depending on your response to JANTOVEN.

- **You must have regular blood tests and visits with your healthcare provider to monitor your condition.**
- **If you miss a dose of JANTOVEN, call your healthcare provider.** Take the dose as soon as possible on the same day. **Do not** take a double dose of JANTOVEN the next day to make up for a missed dose.
- Call your healthcare provider right away if you:
 - take too much JANTOVEN
 - 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 JANTOVEN?

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

What are the possible side effects of JANTOVEN?

JANTOVEN may cause serious side effects including:

- See **“What is the most important information I should know about JANTOVEN?”**
 - **Death of skin tissue (skin necrosis or gangrene).** This can happen soon after starting JANTOVEN. 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.

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the side effects of JANTOVEN. 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 JANTOVEN?

- Store JANTOVEN at 20° to 25°C (68° to 77°F). Excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.]
- Keep JANTOVEN in a tightly closed container, and keep JANTOVEN out of the light and moisture.
- Follow your healthcare provider or pharmacist instructions about the right way to throw away outdated or unused JANTOVEN.
- Females who are pregnant should not handle crushed or broken JANTOVEN tablets.

Keep JANTOVEN and all medicines out of the reach of children.

General information about JANTOVEN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use JANTOVEN for a condition for which it was not prescribed. Do not give JANTOVEN to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about JANTOVEN. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about JANTOVEN that is written for healthcare professionals.

If you would like more information, go to www.upsher-smith.com or call 1-800-654-2299.

What are the ingredients in JANTOVEN?

Active ingredient: Warfarin Sodium, USP

Inactive ingredients: Lactose monohydrate, magnesium stearate, povidone, and pregelatinized starch (corn). The following tablets contain:

- 1 mg: FD&C Red #40 Aluminum Lake
- 2 mg: FD&C Blue #2 Aluminum Lake and FD&C Red #40 Aluminum Lake
- 2½ mg: D&C Yellow #10 Aluminum Lake and FD&C Blue #1 Aluminum Lake
- 3 mg: Brown #75 Synthetic Brown Iron Oxide
- 4 mg: FD&C Blue #1 Aluminum Lake
- 5 mg: FD&C Yellow #6 Aluminum Lake
- 6 mg: Yellow #10 Synthetic Yellow Iron Oxide, Black #85 Synthetic Black Iron Oxide and FD&C Blue #1 Aluminum Lake
- 7½ mg: D&C Yellow #10 Aluminum Lake and FD&C Yellow #6 Aluminum Lake

This Medication Guide has been approved by the U.S. Food and Drug Administration.

For Medication Guides, please visit www.upsher-smith.com or call 1-888-650-3789.

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