

PATIENT INFORMATION

Propafenone Hydrochloride Tablets USP

What are propafenone hydrochloride tablets?

Propafenone hydrochloride tablets are a prescription medicine that is used:

- in certain people who have ventricular heart rhythm disorders
 - to increase the amount of time between having symptoms of heart rhythm disorders called atrial fibrillation (AF) or paroxysmal supraventricular tachycardia (PSVT)
- It is not known if propafenone hydrochloride tablets are safe and effective in children.

Who should not take propafenone hydrochloride tablets?

Do not take propafenone hydrochloride tablets if you have:

- heart failure (weak heart)
- had a recent heart attack
- a heart rate that is too slow, and you do not have a pacemaker
- a heart condition called Brugada Syndrome
- very low blood pressure
- certain breathing problems that make you short of breath or wheeze
- certain abnormal body salt (electrolyte) levels in your blood

Talk to your doctor before taking propafenone hydrochloride tablets if you think you have any of the conditions listed above.

What should I tell my doctor before taking propafenone hydrochloride tablets?

Before you take propafenone hydrochloride tablets, tell your doctor if you:

- have liver or kidney problems
- have breathing problems
- have symptoms including diarrhea, sweating, vomiting, or loss of appetite or thirst that are severe. These symptoms may be a sign of abnormal electrolyte levels in your blood.
- have myasthenia gravis
- have lupus erythematosus
- have been told you have or had an abnormal blood test called Antinuclear Antibody Test or ANA Test
- have any other medical conditions
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. Propafenone hydrochloride tablets can pass into your milk. You and your doctor should discuss the best way to feed your baby during this time.

Tell your doctor about all the medicines you take. including prescription and over-the-counter medicines, vitamins, and herbal supplements. Propafenone hydrochloride tablets and certain other medicines can affect (interact with) each other and cause serious side effects. You can ask your pharmacist for a list of medicines that interact with propafenone hydrochloride tablets.

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

How should I take propafenone hydrochloride tablets ?

- Take propafenone hydrochloride tablets exactly as prescribed. Your doctor will tell you how many tablets to take and how often to take them.
- To help reduce the chance of certain side effects, your doctor may start you with a low dose of propafenone hydrochloride tablets, and then slowly increase the dose.
- You should not drink grapefruit juice during treatment with propafenone hydrochloride tablets.
- If you miss a dose of propafenone hydrochloride tablets, take your next dose at the usual time. Do not take 2 doses at the same time.
- If you take too much propafenone hydrochloride tablets, call your doctor or go to the nearest hospital emergency room right away.
- Call your doctor if your heart problems get worse.

What are possible side effects of propafenone hydrochloride tablets?

Propafenone hydrochloride tablets can cause serious side effects including:

- **New or worsened abnormal heart beats that can cause sudden death or be life-threatening.** Your doctor may do an electrocardiogram (ECG or EKG) before and during treatment to check your heart for these problems.
- **New or worsened heart failure. Tell your doctor about any changes in your heart symptoms, including:**
 - any new or increased swelling in your arms or legs
 - trouble breathing
 - sudden weight gain
- **Effects on pacemaker function.** Propafenone hydrochloride tablets may affect how an implanted pacemaker or defibrillator works. Your doctor should check how your pacemaker or defibrillator is working during and after treatment with propafenone hydrochloride tablets. They may need to be re-programmed.

- **Very low white blood cell levels in your blood (agranulocytosis).** Your bone marrow may not produce enough of a certain type of white blood cells called neutrophils. If this happens, you are more likely to get infections. Tell your doctor right away if you have any of these symptoms, especially during the first 3 months of treatment:

- fever
- sore throat
- chills
- **Worsening of myasthenia gravis in people who already have this condition.** Tell your doctor about any change in your symptoms.

- **Propafenone hydrochloride tablets may cause lower sperm counts in men.** This could affect the ability to father a child. Talk to your doctor if this is a concern for you.

Common side effects of propafenone hydrochloride tablets include:

- unusual taste
- nausea
- vomiting
- dizziness
- constipation
- headache
- tiredness
- irregular heartbeats

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

These are not all the possible side effects of propafenone hydrochloride tablets. For more information, ask your doctor 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 propafenone hydrochloride tablets?

- Store propafenone hydrochloride tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the bottle tightly closed.

Keep propafenone hydrochloride tablets and all medicines out of the reach of children.

General information about propafenone hydrochloride tablets Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use propafenone hydrochloride tablets for a condition for which it was not prescribed. Do not give propafenone hydrochloride tablets to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about propafenone hydrochloride tablets that is written for health professionals. For more information about propafenone hydrochloride tablets, call 1-800-308-6755.

What are the ingredients in propafenone hydrochloride tablets?

Active ingredient: Propafenone hydrochloride.

Inactive ingredients: Corn starch, croscarmellose sodium, hypromellose, maltodextrin, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silicon dioxide colloidal, titanium dioxide, and triacetin.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured by:
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The logo for ANI Pharmaceuticals, Inc. features the lowercase letters "ani" in a bold, italicized, sans-serif font. Below the letters, the words "Pharmaceuticals, Inc." are written in a smaller, plain sans-serif font.

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