The dose of propafenone hydrochloride tablets must be individually titrated on the basis of response and tolerance. Initiate treatment with 150 mg 3 times a day and titrate the dose upward in 150 mg increments at intervals of at least 3 days based on response and tolerance. Treatment should not exceed 450 mg total dose (3 times 150 mg) in a 24-hour period.

Propafenone should be used with caution in patients with structural heart disease, AV nodal refractoriness, or ventricular arrhythmia who have not previously been treated with a Class IC antiarrhythmic agent.

Propafenone can cause side effects that may be serious, including worsening of ventricular arrhythmias such as ventricular fibrillation, ventricular tachycardia, asystole, and torsade de pointes. It may also cause new or worsened atrial fibrillation, atrial flutter, atrial tachycardia, paroxysmal supraventricular tachycardia, paroxysmal atrial fibrillation, atrial flutter, junctional rhythm, atrioventricular nodal escape rhythm, and atrioventricular nodal reentry tachycardia.

Propafenone has caused new or worsened arrhythmias. Such proarrhythmic effects include sudden death and life-threatening ventricular arrhythmias such as ventricular fibrillation, ventricular tachycardia, asystole and torsade de pointes. It may also cause new or worsened atrial fibrillation, atrial flutter, atrial tachycardia, paroxysmal supraventricular tachycardia, paroxysmal atrial fibrillation, atrial flutter, junctional rhythm, atrioventricular nodal escape rhythm, and atrioventricular nodal reentry tachycardia.

Propafenone may also cause new or worsening of atrial fibrillation, atrial flutter, atrial tachycardia, paroxysmal supraventricular tachycardia, paroxysmal atrial fibrillation, atrial flutter, junctional rhythm, atrioventricular nodal escape rhythm, and atrioventricular nodal reentry tachycardia.

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**Hemodynamics**

In U.S. long-term safety trials, 474 patients (mean age: 57.4 ± 14.5 years) with supraventricular arrhythmias [195 with PAF, 195 with PSVT and 84 with both PAF and PSVT] were treated up to 5 years (mean: 14.4 months) with propafenone. Fourteen patients had documented drug-related serious adverse events or deaths. Three deaths were considered drug-related: two from sudden cardiac death and one from pulmonary embolism. In addition, five patients experienced serious adverse events that were possibly related to propafenone. The relative risk of serious adverse events or death in the propafenone treatment group was similar to that in the placebo group.

**CONTRAINDICATIONS**

Propafenone is contraindicated in patients with hepatic or renal impairment, and in patients with uncorrected sick sinus syndrome, atrioventricular block, sick sinus syndrome, and uncorrected ventricular bigeminy.

**PRECAUTIONS**

Propafenone exhibits potential for accumulation to a significant degree at steady state, and for the development of tolerance to the antiarrhythmic effects when administered in multiple doses.

**Hepatic Impairment:**

There are significant differences in plasma concentrations of propafenone in slow and extensive metabolizers, the former metabolizing the drug more rapidly and extensively than the latter. The implications of these metabolic differences for the potential for accumulation of propafenone to affect the antiarrhythmic effects are not known. As a consequence of the described metabolic differences, the potential for drug interactions involving propafenone should be considered for patients in whom drug interactions are of concern.

**Renal Impairment:**

The effect of renal impairment on the disposition of propafenone has not been evaluated in humans. Therefore, no dosage adjustment is recommended for these patients.

**ECG Changes:**

Electrocardiographic changes are common in patients treated with propafenone. These changes can be seen within 1 to 2 days after starting therapy, persist during therapy, and subside in most patients upon discontinuation of the drug. Electrocardiographic changes include prolonged PR, QRS, and QT intervals; atrioventricular block; and first-degree atrioventricular block. In patients with atrial fibrillation, the atrial rate may also be reduced. Changes in the QRS interval of patients with atrial fibrillation may alter the use of atrioventricular sequential pacing to control the ventricular rate.

**Arrhythmias:**

Arrhythmias, including ventricular tachycardia and ventricular fibrillation, have been reported in patients receiving propafenone therapy. The risk of these arrhythmias is increased in patients with concomitant electrolyte disorders, hypokalemia, and hyperkalemia. The risk of these arrhythmias is also increased in patients with concomitant cardiac disease, particularly those with proarrhythmic potential. The use of propafenone in patients with concomitant cardiac disease may increase the risk of arrhythmias.

**Drug Interactions:**

Propafenone is known to interact with a number of other drugs. These interactions may result in changes in the pharmacokinetics or pharmacodynamics of other drugs. The potential for drug interactions involving propafenone should be considered for patients in whom drug interactions are of concern.

**Electrolyte Balance:**

If patients experience symptoms that may be associated with altered electrolyte balance, such as excessive or decreased sweating, or difficulty in maintaining daily fluid intake, the possibility of hypokalemia or hyperkalemia should be considered.

**OVERDOSAGE:**

The management of propafenone overdose is symptomatic and supportive. In general, the treatment of propafenone overdose should be based on the severity of the symptoms and on the likelihood of a toxic effect. In cases of suspected propafenone overdose, the patient should be observed closely for the onset of signs and symptoms of toxicity. The patient should be monitored for cardiac arrhythmias, hypotension, and sedation. Treatment of overdose may include hemodynamic monitoring, oxygenation, and treatment for bradycardia or asystole.

**SUPPLEMENTAL INFORMATION**

See FDA-approved patient labeling (Patient Information).

**REPLICA**:

**DISPENSE** in a tight, light-resistant container as defined in the USP .

**REFERENCES**

New or worsened abnormal heart beats, that can be severe. These symptoms may be a sign of abnormal electrolyte levels in your blood.

• have been told you have or had an abnormal blood test called atrial fibrillation (AF) or paroxysmal supraventricular tachycardia (PVT)

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

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 serious 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 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 life-threatening problems. Your doctor may do an electrocardiogram (ECG or EKG) before and during treatment to check your heart for these problems.

• 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?

• Heart rhythm disorders (such as atrial fibrillation or paroxysmal supraventricular tachycardia)

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• a heart rate that is too slow, and you do not have a pacemaker

A heart condition called Brugada Syndrome
• very low blood pressure

Some of these problems may be caused by 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 (PVT)

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Who should not take propafenone hydrochloride tablets?
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 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
- constipation
- nausea
- headache
- vomiting
- diarrhea
- dizziness
- irregular heart beats

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.

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 1-800-444-4011.

What are the ingredients in propafenone hydrochloride tablets?

Active ingredient: propafenone hydrochloride

Inactive ingredients: camu camu wax, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized corn starch, sodium starch glycolate, stearyl acid, titanium dioxide and tricolorin.

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

Manufacutred for:

QUALITEST PHARMACEUTICALS
Huntsville, AL 35811
8183640 Revised 1/2016 R1

Client: Par Pharmaceutical NC
Proof ID: 224723-1
Order Date: 4/14/2016

Colors: X
Orientation: Head to Head - Back

Item # 8182244
Fiat Size: 12.25" x 11.25"

Perforation: Dashed Line Print, Does Not Perf Mic:

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