Hearing impaired, tinnitus, vertigo.

In U.S. trials for 623 patients with a history of symptomatic atrial fibrillation treated with propafenone ER capsules, in patients with concurrent adventitious atrial fibrillation, or in patients with atrial fibrillation, use of propafenone ER capsules with drugs that increase the atrioventricular nodal refractory period can cause and/or worsen AV block. Propafenone exerts a negative inotropic activity on the myocardium as well as beta blockade effects and a calcium channel antagonist activity. In vitro studies (i.e., isolated guinea pig strips) have shown that propafenone reduces myocardial contractility; although this calcium antagonist effect probably does not contribute to antiarrhythmic effects, it may be of clinical importance in patients with structural heart disease or hypertension. Propafenone HCl occurs as colorless crystals or white crystalline powder with a very bitter taste. It is very slightly soluble in water and freely soluble in ethanol.

Of the total number of subjects in Phase 3 clinical studies of propafenone ER capsules (propafenone 100 mg/day, 200 mg/day, 300 mg/day, 400 mg/day), 1.2% discontinued due to adverse events. The most frequently reported adverse events that occurred in > 2% and ≤ 5% of patients include: headache (4.4%), constipation (2.6%), nausea (2.6%), dizziness (2.2%), diarrhea (2.1%), cough (2.0%), and coughing (2.0%). The incidence of drug-related events was not greater than reported for placebo (excluding those not reasonably associated with the use of the drug or not drug related). Other adverse events reported in ≥ 1% of patients taking propafenone ER capsules include: upper respiratory tract infection (2.3%), blood alkaline phosphatase increased (2.3%), and greater than placebo). Propafenone is indicated for the treatment of chronic atrial fibrillation (AF) in patients with and during the first week of therapy, late events also were seen and the CAST study showed that the rate of death or reversed cardiac arrest rate (7.7%; 56/730) was seen in patients treated with propafenone for atrial fibrillation/flutter who do not have symptoms of the Brugada Syndrome. Evaluate patients via ECG after initiation of therapy.

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Studies in humans have shown that propafenone exerts a negative inotropic effect on the heart muscle. As a consequence of the observed differences in metabolism, administration of propafenone ER capsules should be avoided in patients who are slow metabolizers of CYP2D6 enzymes. The metabolite is not formed or is minimally formed. In these patients, the estimated propafenone elimination half-life increased and the clearance of propafenone from the prolonged-release preparations resulted in an increase of overall first pass metabolism. The 325 mg immediate release tablet had an absolute bioavailability of 10.6%. Absorption from a 300 mg dose of propafenone is reduced and the elimination half-life increased in patients with significant hepatic dysfunction. Protein binding decreases to about 88% in patients with severe hepatic dysfunction. The clearance of propafenone is reduced and the elimination half-life increased in patients with significant renal dysfunction. The elimination half-life of propafenone is prolonged in patients with impaired hepatic function. In serum, propafenone is greater than 95% bound to proteins within the concentration range of 0.5 to 10 μg/mL. Propafenone is a substrate for organic cation transporters (OCT2 and OCT3) and is transported against a concentration gradient. Acute liver failure increases the bioavailability of propafenone.

**Dosage**

In adults, propafenone HCl ER capsules are available in 135 mg, 225 mg, and 325 mg extended release capsules. The recommended dosages for patients with normal renal function are as follows:

- 135 mg extended release capsule once daily
- 225 mg extended release capsule twice daily
- 325 mg extended release capsule twice daily

Patients with impaired renal function require a dosage adjustment. Patients with severe renal impairment, a dosage adjustment is required.

**How should I store propafenone HCl ER capsules?**

Store propafenone HCl ER capsules at room temperature between 59°F to 86°F (15°C to 30°C). Keep the bottle tightly closed.

Keep propafenone HCl ER capsules and all medicines out of the reach of children.

**What are the ingredients in propafenone HCl ER capsules?**

Active Ingredient: Propafenone hydrochloride

Inactive Ingredients: hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate and red and white dyes. In addition, the 325 mg capsule also contains FD&C Blue No. 1, D&C Yellow No. 10 and FD&C Red No. 40 and the 425 mg capsule contains FD&C Blue No. 1, FD&C Red No. 40 and FD&C Yellow No. 6. The black ink contains D&C Black, FD&C Yellow No. 5, FD&C Blue No. 2, FD&C Red No. 40, FD&C Blue No. 1 and shellac-glaze-45% (20% wertified) in ethanol.

**Manufactured by**

Par Pharmaceutical Companies Inc.

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