Propafenone
Injections, tablets film-coated

Drug description :
Each tablet contains 150 mg or 300mg propafenone Hcl.

Indications :
Propafenone is indicated for the prophylaxis and treatment of ventricular arrhythmias. Propafenone is also indicated for the prophylaxis and treatment of paroxysmal supraventricular tachyarrhythmias which include paroxysmal atrial flutter/fibrillation and paroxysmal re-entrant tachycardias involving the AV node or accessory bypass tracts, when standard therapy has failed or is contra-indicated.

Adult Dosage :
It is recommended that Propafenone therapy should be initiated under hospital conditions, by a physician experienced in the treatment of arrhythmias. The individual maintenance dose should be determined under cardiological surveillance including ECG monitoring and blood pressure control. If the QRS interval is prolonged by more than 20%, the dose should be reduced or discontinued until the ECG returns to normal limits.

Adults: Initially, 150 mg three times daily increasing at a minimum of three-day intervals to 300 mg twice daily and if necessary, to a maximum of 300 mg three times daily.
The tablets should be swallowed whole and taken with a drink after food. A reduction in the total daily dose is recommended for patients below 70 kg bodyweight.
Dosage in impaired liver function: Propafenone is extensively metabolised via a saturable hepatic oxidase pathway. In view of the increased bioavailability and elimination half-life of propafenone, a reduction in the recommended dose may be necessary.

Dosage in impaired renal function: Although the elimination of propafenone and its major metabolite is not affected by renal impairment, Propafenone should be administered cautiously.

Child Dosage :
A suitable dosage form of Propafenone for children is not available.

Elderly Dosage :
Higher plasma concentrations of propafenone have been noted during treatment. Elderly patients may therefore respond to a lower dose.

Contra Indications :
Known hypersensitivity to propafenone or to any of the other ingredients.
Propafenone is contra-indicated in patients with uncontrolled congestive heart failure, cardiogenic shock (unless arrhythmia-induced), severe bradycardia, uncontrolled electrolyte disturbances, severe obstructive pulmonary disease or marked hypotension.

Propafenone may worsen myasthenia gravis.
Unless patients are adequately paced, Propafenone should not be used in the presence of sinus node dysfunction, atrial conduction defects, second degree or greater AV block, bundle branch block or distal block.
Minor prolongation of the PR interval and intra-ventricular conduction defects (QRS duration of less than 20%) are to be expected during treatment

Special Precautions :
The weak negative inotropic effect of Propafenone may assume importance in patients predisposed to cardiac failure.
In common with other anti-arrhythmic drugs, Propafenone has been shown to alter sensitivity and pacing threshold. In patients with pacemakers, appropriate adjustments may be required.
There is potential for conversion of paroxysmal atrial fibrillation to atrial flutter with accompanying 2:1 or 1:1 conduction block.
Because of the beta-blocking effect, care should be exercised in the treatment of patients with obstructive airways disease or asthma.
As with other class IC anti-arrhythmic agents, patients with structural heart disease may be predisposed to serious adverse effects.
It is essential that each patient given Propafenone be evaluated electrocardiographically and clinically prior to and during therapy to determine whether the response to Propafenone supports continued treatment.

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Interactions :

The effects of Propafenone may be potentiated if it is given in combination with other local anaesthetic type agents or agents which depress myocardial activity.
Propafenone has been shown to increase the plasma levels of digoxin and caution should be exercised with regard to digitalis toxicity.
Propafenone has been shown to increase the plasma levels of oral anticoagulants, with an accompanying increase in prothrombin time, which may require a reduction in the dose of oral anticoagulants.
Plasma levels of propafenone may be increased by concomitant administration of cimetidine.
Increased propranolol and metoprolol plasma levels have been observed when these beta-blockers were used concurrently with Propafenone. Thus, dose reduction of these beta-blockers may be required. Details of interactions with other beta-blockers are not known.

Coadministration of propafenone hydrochloride with drugs metabolised by CYP2D6 (such as venlafaxine) might lead to increased levels of these drugs.
Drugs that inhibit CYP2D6, CYP1A2 and CYP3A4, e.g. ketoconazole, cimetidine, quinidine, tropisetron, dolasetron, mizolastine, erythromycin and grapefruit juice may lead to increased levels of propafenone hydrochloride. When propafenone hydrochloride is administered with inhibitors of these enzymes, the patients should be closely monitored and the dose adjusted accordingly.
Due to the potential for increased plasma concentrations, co-administration of 800-1200mg/day doses of ritonavir and propafenone hydrochloride is contraindicated.
Combination therapy of amiodarone and propafenone hydrochloride can affect conduction and repolarisation and lead to abnormalities that have the potential to be proarrhythmic. Dose adjustments of both compounds based on therapeutic response may be required.

No significant effects on the pharmacokinetics of propafenone or lidocaine have been seen following their concomitant use in patients. However, concomitant use of propafenone hydrochloride and intravenous lidocaine have been reported to increase the risks of central nervous system side effects of lidocaine.
Phenobarbital is a known inducer of CYP3A4. Response to propafenone hydrochloride therapy should be monitored during concomitant chronic phenobarbital use.

There has been a report of the lowering of propafenone levels by rifampicin, via the hepatic mixed oxidase system. This reduction may lead to breakthrough arrhythmias.
Cases of possible interactions with cyclosporin (levels increased with deterioration in renal function), theophylline (levels increased), desipramine (levels increased) have also been reported.

Due to the arrhythmogenic effects of tricyclic and related antidepressants and/or neuroleptics, these drugs may interact adversely when used concomitantly with anti-arrhythmic drugs including propafenone.
Concomitant administration of propafenone hydrochloride and fluoxetine in extensive metabolisers increased the S propafenone Cmax and AUC by 39 and 50% and the R propafenone Cmax and AUC by 71 and 50%. Elevated levels of plasma propafenone may occur when propafenone hydrochloride is used concomitantly with paroxetine. Lower doses of propafenone may be sufficient to achieve the desired therapeutic response.

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries. www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

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