FLECARITE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **Flecarite** [Flecainide acetate B.P 50 /100mg tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Flecainide is a class I anti-arrhythmic drug. Flecainide slows conduction through the heart, having its greatest effect on His Bundle conduction. It also acts selectively to increase anterograde and particularly retrograde accessory pathway refractoriness. Its actions may be reflected in the ECG by prolongation of the PR interval and widening of the QRS complex. **INDICATION**: Flecainide tablets are indicated for: a) AV nodal reciprocating tachycardia; arrhythmias associated with Wolff-Parkinson-White Syndrome and similar conditions with accessory pathways. b) Paroxysmal atrial fibrillation in patients with disabling symptoms and in the absence of left ventricular dysfunction. c) Symptomatic sustained ventricular tachycardia. d) Premature ventricular contractions and/or non-sustained ventricular tachycardia which are causing disabling symptoms. Can be used for the maintenance of normal rhythm following conversion by other means

DOSAGE AND ADMINISTRATION: **ADULTS:** Supraventricular arrhythmias: Recommended starting dosage is 50mg twice daily and may be increased to a maximum of 300mg daily. Ventricular arrhythmias: Recommended starting dosage is 100mg twice daily. The maximum daily dose is 400mg. children: Flecainide is not recommended in children under 12. **CONTRAINDICATION:** In cardiac failure and in patients with a history of myocardial infarction with either asymptomatic ventricular ectopics or asymptomatic non-sustained ventricular tachycardia, in patients with long standing atrial fibrillation with no attempt to convert to sinus rhythm, and in patients with haemodynamically significant valvular heart disease. Flecainide should not be given to patients with sinus node dysfunction, atrial conduction defects, second degree or greater atrio-ventricular block, bundle branch block or distal block unless pacing resuce is available. Flecainide is contra-indicated in case of hypertensitivity to the active substance or any of excipients. **WARNINGS & PRECAUTIONS**: Mortality in patients with asymptomatic non-life-threatening ventricular arrhythmias who had a myocardial infarction more than six days but less than two years previously, ventricular Pro-arrhythmic Effects in Patients with Atrial Fibrillation/ Flutter, electrolyte disturbances should be corrected before using Flecainide, caution should be exercise in hepatic impairment patient, all patients with permanent pacemakers or temporary pacing electrodes and patients with acute onset of atrial fibrillation following cardiac surgery. Avoided in patients with structural organic heart disease or abnormal left ventricular function. **DRUG INTERACTIONS**: Cardiac glycosides, class ii anti-arrhythmics, class III anti-arrhythmics, class IV anti-arrhythmics, anti-depressants, clozapine, mizolastine, terfenadine, quinine, antivirals, diuretics, cimetidine, bupropion **ADVERSE REACTIONS:** Asthenia, fatigue, fever, oedema, pro-arrhythmic effects, AV block-second-degree and third degree, bradycardia, cardiac failure/congestive cardiac failure, chest pain, hypotension, myocardial infarction, palpitation and sinus pause or arrest and tachycardia (AT or VT), rashes, alopecia, urticaria, photosensitivity, increases in anti-nuclear antibodies, reductions in red and white blood cells, hallucinations, depression, confusion, amnesia, anxiety, insomnia, abdominal pain, anorexia, constipation, diarrhoea, dyspepsia, flatulence, elevated liver enzymes, jaundice, giddiness, dizziness, lightheadedness, visual disturbances and dyspnoea.

MARKETED BY:

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(Additional information is available on request)