JAMP Flecainide Acetate Tablet USP 100mg
Product Information

PRODUCT DESCRIPTION
White to off-white round shaped, biconvex tablets, scored and engraved "FL" over "100" on one side and plain on other side. The tablet can be divided into equal halves.
Each tablet contains flecainide acetate 100mg.
Excipients include microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, magnesium stearate, hydrogenated vegetable oil.

Uses
JAMP Flecainide is a potent sodium channel blocking agent for the treatment of the conditions listed below. It is recommended that treatment with JAMP Flecainide should be initiated in hospitals.
JAMP Flecainide slows conduction through the heart, its actions may be reflected in the ECG by prolongation of the PR interval and widening of the QRS complex. The effect on the JT interval is insignificant at therapeutic levels.

INDICATIONS
JAMP 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. Arrhythmias of recent onset will respond more readily.
c) Symptomatic sustained ventricular tachycardia.
d) Premature ventricular contractions and/or non-sustained ventricular tachycardia which are causing disabling symptoms, where these are resistant to other therapy or when other treatment has not been tolerated. JAMP Flecainide tablets can be used for the maintenance of normal rhythm following conversion by other means.

DOSAGE AND ADMINISTRATION
For oral use only.
- **Adults:**
  Supraventricular arrhythmias: the recommended starting dosage is 50mg twice daily and most patients will be controlled at this dose. If required the dose may be increased to a maximum of 300mg daily.

  Ventricular arrhythmias: the recommended starting dosage is 100mg twice daily.
  The maximum daily dose is 400mg and this is normally reserved for patients of large build or where rapid control of the arrhythmia is required. After 3-5 days it is recommended that the dosage be progressively adjusted to the lowest level which maintains control of the arrhythmia. It may be possible to reduce dosage during long-term treatment.

- **Children:**
  JAMP Flecainide is not recommended in children under 12, as there is insufficient evidence of its use in this age group.

- **Elderly Patients:**
  The rate of flecainide elimination from plasma may be reduced in elderly people. This should be taken into consideration when making dose adjustments.

- **Plasma Levels:**
  Based on PVC suppression, it appears that plasma levels of 200-1000 ng/mL may be needed to obtain the maximum therapeutic effect. Plasma levels about 700-1000 ng/mL are associated with increased likelihood of adverse experience.

- **Dosage in Impaired Renal Function:**
  In patients with significant renal impairment (creatinine clearance of 35 mL/ min/1.73sq.m. or less) the maximum initial dosage should be 100mg daily (or 50mg twice daily). When used in such patients, frequent plasma level monitoring is strongly recommended.

CONTRAINDICATIONS
JAMP Flecainide is contraindicated in cardiac failure, and in patients with a history of myocardial infarction who have either asymptomatic ventricular ectopics or nonsustained ventricular tachycardia.
It is also contraindicated in patients with long standing atrial fibrillation in whom there has been no attempt to convert to sinus rhythm and in patients with haemodynamically significant valvular heart disease.
Unless pacing rescue is available, JAMP Flecainide should not be given to patients with sinus node dysfunction, atrial conduction defects, second degree or greater atrioventricular block, bundle branch block or distal block.

WARNING AND PRECAUTIONS
1. Electrolyte disturbances should be corrected before using JAMP Flecainide.
2. Since flecainide elimination from the plasma can be markedly slower in patients with significant hepatic impairment, flecainide should not be used in such patients unless the potential benefits clearly outweigh the risks. Plasma level monitoring is strongly recommended in these circumstances.
3. JAMP Flecainide is known to increase endocardial pacing thresholds – ie to decrease endocardial pacing sensitivity.This effect is reversible and is more marked on the acute pacing threshold than on the chronic. JAMP Flecainide should thus be used with caution in all patients with permanent pacemakers or temporary pacing electrodes, and should not be administered to patients with existing poor thresholds or non-programmable pacemakers unless suitable pacing rescue is available.
4. Generally, a doubling of either pulse width or voltage is sufficient to regain capture, but it may be difficult to obtain ventricular thresholds less than 1 volt at initial implantation in the presence of JAMP Flecainide.
5. The minor negative inotropic effect of flecainide may assume importance in patients predisposed to cardiac failure.
   Difficulty has been experienced in defibrillating some patients. Most of the cases reported had pre-existing heart disease with cardiac enlargement, a history of myocardial infarction, arterio-sclerotic heart disease and cardiac failure.
6. JAMP Flecainide should be used with caution in patients with acute onset of atrial fibrillation following cardiac surgery.
7. In a large scale, placebo-controlled clinical trial in post-myocardial infarction patients with asymptomatic ventricular arrhythmia, oral flecainide was associated with a 2.2 fold higher incidence of mortality or non-fatal cardiac arrest as compared with its matching placebo. In that same study, an even higher incidence of mortality was observed in flecainide-treated patients with more than one myocardial infarction. Comparable placebo-controlled clinical trials have not been done to determine if flecainide is associated with higher risk of mortality in other patients groups.

USE IN PREGNANCY AND LACTATION
There is no evidence as to drug safety in human pregnancy. In New Zealand White rabbits high doses of flecainide caused some foetal abnormalities, but these effects were not seen in Dutch Belted rabbits or rats. The relevance of these findings to humans has not been established. Data have shown that flecainide crosses the placenta to the foetus in patients taking flecainide during pregnancy.
Flecainide is excreted in human milk and appears in concentrations which reflect those in maternal blood. The risk of adverse effects to the nursing infant is very small. The benefit of JAMP Flecainide during lactation should therefore be weighted against possible effects on the child.

DRUG INTERACTIONS
Use of flecainide with other sodium channel blockers is not recommended.
Treatment with JAMP Flecainide is compatible with use of oral anti-coagulants. Flecainide can cause the plasma digoxin level to rise by about 15%, which is unlikely to be of clinical significant for patients with plasma levels in the therapeutic range. It is recommended that the digoxin plasma level in digitalised patients should be measured not less than six hours after any digoxin dose, before or after administration of flecainide. The possibility of additive negative inotropic effects of beta-blockers and other cardiac depressants with flecainide should be recognised.
Limited data in patients receiving known enzyme inducers (phenytoin, phenobarbital, carbamazepine) indicate only a 30% increase in the rate of flecainide elimination. In healthy subjects receiving cimetidine (1g daily) for one week, plasma flecainide levels increased by about 30% and the half-life increased by 10%.
When flecainide is given in the presence of amiodarone, the usual flecainide dosage should be reduced by 50% and the patient monitored closely for adverse effects. Plasma level of monitoring is strongly recommended in these circumstances.

SIDE EFFECTS
Cardiac: Pro-arrhythmic effects occur but are most likely in patients with structural heart disease and/or significant left ventricular impairment.
In patients with atrial flutter the use of JAMP Flecainide has been associated with 1:1 AV conduction following initial atrial slowing with resultant ventricular acceleration.
This has been seen most commonly following the use of the injection for acute conversion. This effect is usually short lived and abates quickly following cessation of therapy.

Dermatological:	There have been isolated cases of photosensitivity.
Gastrointestinal:	Nausea and vomiting.
Hepatic:	A number of cases of elevated liver enzymes and jaundice have been reported in association with JAMP Flecainide treatment. So far this has always been reversible on stopping treatment.
Neurological:	Most commonly giddiness, dizziness and light-headedness which are usually transient.
Opthalmological:	Visual disturbances, such as double vision and blurring of vision may occur but these are usually transient and disappear upon continuing or reducing the dosage.

During long term therapy a few cases of peripheral neuropathy, parasthesia and ataxia have been reported. Extremely rare cases of corneal deposits, pulmonary fibrosis, interstitial lung disease and pneumonitis have also been reported.

OVERDOSAGE
No specific antidote is known. There is no known way of rapidly removing flecainide from the system, but forced acid diuresis may theoretically be helpful. Neither dialysis nor haemoperfusion is helpful and injections of anticholinergics are not recommended. Treatment may include therapy with an inotropic agent, intravenous calcium, giving circulatory assistance (eg: balloon pumping), mechanically assisting respiration, or temporarily inserting a transvenous pacemaker if there are severe disturbances or the patient's left ventricular function is otherwise compromised.

STORAGE
Store at or below 30°C.

PACK SIZE
Available in Alu-PVC/PVdC blister of 30's tablets. Such 2 blisters are kept in a carton. - packs of 60 tablets.

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