### Alert

Use in consultation with a Paediatric Cardiologist. Contraindicated in infants with reduced myocardial contractility. Use caution in patients with congenital heart disease—increased potential for proarrhythmic effects. Intravenous flecainide needs close cardiorespiratory monitoring due to the potential for an acute deterioration.

### Indication

Treatment of paroxysmal supraventricular tachycardia, paroxysmal atrial fibrillation/flutter and life-threatening ventricular dysrhythmias as a second-line agent where tachycardia has been resistant to first-line agents.

### Action

Flecainide causes a decrease in intracardiac conduction for all parts of the heart, with the greatest effect in the His-Purkinje system. It acts by blocking fast sodium channels. As a type IC agent, it slows cardiac conduction and decreases contractility.

### Drug Type

Type Ic antiarrhythmic.

### Trade Name

Flecainide Sandoz Tablets; Flecatab Tablets; Tambocor solution for injection, Tambocor Tablets

### Presentation

Intravenous: 10 mg/mL (15 mL) injection. Oral: Flecainide 20 mg/mL suspension compounded by pharmacy. 50 mg, 100 mg tablets.

### Dosage/Interval

**Oral:**
Start at 1 mg/kg/dose 8 or 12 hourly. Increase by 1 mg/kg/dose as necessary to achieve maintenance of sinus rhythm up to maximum dose. Intravenous: 2 mg/kg over at least 10 minutes.

### Route

Oral [preferred route] or intravenous.

### Maximum Daily Dose

8 mg/kg/day.

### Preparation/Dilution

Draw up 1mL (10mg of flecainide) and add 9mL of glucose 5% make up a final volume of 10 mL with a concentration of 1mg/mL. It can also be administered undiluted.

### Administration

**Oral:**
Administer between milk feeds. Do not administer with milk. Milk decreases absorption in infants.

**Intravenous:**
IV infusion over at least 10 minutes. IV flecainide needs to be monitored very closely with the potential for an acute deterioration.

### Monitoring

Initiate treatment in hospital with ECG monitoring in consultation with paediatric cardiologist. When intravenous route is used, continuous ECG monitoring is mandatory. Perform ECG when the dosage is increased — monitor QRS duration and dysrhythmia. Therapeutic trough concentrations are not routinely required (200–1000 microgram/L).

### Contraindications

Cardiogenic shock. Hypersensitivity to flecainide. Significant renal impairment (creatinine clearance < 50 mL/min). Reduced left ventricular ejection fraction.

### Precautions

Use with caution in patients with congenital heart disease or conduction system disease (right bundle branch block, with left hemiblock and without pacemaker; second- or third-degree atrioventricular block, without pacemaker; sick sinus syndrome [bradycardia-tachycardia syndrome]). Milk decreases oral flecainide absorption. Consider decreasing oral dose or dose monitoring if change of milk diet.
Dosing adjustments are required in infants with renal impairment because 10% to 50% of a flecainide dose is excreted in the urine. Use with caution in significant hepatic impairment.

**Drug Interactions**

Drugs prolonging QT interval (cisapride, amiodarone, clarithromycin, chloral hydrate, ciprofloxacin, erythromycin, octreotide, sodium phosphate, vasopressin, ketoconazole, fluconazole, hydrochlorothiazide, azithromycin, propranolol, digoxin, verapamil).

**Adverse Reactions**

**Adults:**
- **Common**
  - Cardiovascular: Palpitations (6.1%);
  - Gastrointestinal: Nausea (up to 10%);
  - Neurological: Dizziness (18.9% to 30%), Headache (4.5% to 9.6%);
  - Ophthalmological: Blurred vision (10% to 38%), Photopsia (up to 30%);
  - Respiratory: Dyspnoea (up to 10.3%);
  - Other: Fatigue (7.7%).

- **Serious**
  - Cardiac arrest, cardiac dysrhythmia, cardiogenic shock, disorder of pacing function, electrocardiogram abnormalities, heart block, heart failure (new onset or worsening [up to 25.7%]), prolonged QT interval, sinus node dysfunction (1% to less than 3%), syncope (1% to less than 3%), torsades de pointes, ventricular fibrillation, ventricular tachycardia.

- **Children:**
  - Dizziness, blurred vision and headache have been reported in children.

**Compatibility**

5% glucose.

**Incompatibility**

Incompatible with alkaline and chloride-containing solutions.

**Stability**

Diluted solution stable for 24 hours at 25°C.

Oral suspension compounded by Pharmacy stable for up to 60 days.

**Storage**

Ampoules. Store below 30°C. Protect from light.

Tablets. Store below 30°C.

Compounded suspension: Store at room temperature.

**Special Comments**

**Evidence summary**

Efficacy and safety:

A review of published cases and subsequent reports found flecainide appeared to be safe (no deaths with usual oral dosing; < 1% incidence of serious proarrhythmia) and effective (73–100 % control, depending on mechanism) in children with supraventricular tachycardia. [1-4] (LOE IV GOR B) However, concerns regarding safety exist in patients with structural heart disease and cardiomyopathy. The Cardiac Arrhythmia and Suppression Trial (adults with AMI) demonstrated increased mortality in patients who received flecainide. [3-5] A report of young patients (4 days to 26 years) administered flecainide for treatment of SVT (n = 369) or VT (n = 103) found efficacy 71.4%, proarrhythmic response 7.4%, cardiac arrest 2.3% and died during treatment 2.1%. Cardiac arrest and deaths occurred predominantly among patients with underlying heart disease, particularly among patients receiving flecainide for supraventricular tachycardia (8.3%). [3] A report in children (n = 229) with congenital heart disease or cardiomyopathy, incidence of cardiac arrest in patients receiving flecainide was 3.0% with a mortality of 4.3%, with no difference in cardiac arrest or mortality rate when compared to patients who received other antiarrhythmics. [4]

**Guidelines:** For SVT, flecainide is effective as a first-line agent in infants, but typically used as a second-line agent because of its arrhythmogenic potential. It has been used in infants with reentrant supraventricular tachycardia including Wolff-Parkinson-White syndrome, focal atrial tachycardia and permanent junctional reciprocating tachycardia (case reports). Has the potential for proarrhythmia in patients with congenital heart disease. Caution is advised when used in patients with congenital heart disease or conduction system disease. Milk feeds may decrease absorption. Concentration monitoring may assist in guiding therapy. Contraindicated if creatinine clearance <50 mL/min or reduced Left Ventricular Ejection Fraction. [6] (LOE IV GOR B)
### Pharmacokinetics:
Flecainide is cleared via hepatic biotransformation and renal excretion. Infants < 1 year of age had a mean t½ of 11–12 hour; children aged 1 to 12 years had a t½ of 8 hours. Dosing schedules based on mg/m² correlated better with plasma flecainide concentrations than did dosing based on mg/kg.[8, 9] Oral bioavailability in adults reported to be 78–100%.

### References