Flecainide

Newborn use only

2024

Alert	Use in consultation with paediatric cardiologist. Contraindicated in infants with reduced myocardial contractility. Use cautiously in patients with congenital heart disease—increased potential for pro-arrhythmic effects. **Intravenous flecainide needs close cardiorespiratory monitoring. It is only to be used in ICU settings and in the presence of paediatric electrophysiologist.** Flecainide has been associated with life threatening and occasionally fatal ventricular arrhythmias. Use with extreme caution, preferably after other antiarrhythmic drugs have been tried or considered inappropriate.
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	Decreases 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 agent.
Trade name	Flecainide Sandoz Tablets; Flecatab Tablets; Tambocor solution for injection, Tambocor Tablets
Presentation	**Oral**: 20 mg/mL suspension compounded by pharmacy. 50 mg, 100 mg tablets. **IV**: 10 mg/mL injection.
Dose	**Oral (recommended)**: Starting dose: 1 mg/kg/dose 8 or 12 hourly. Increase by 1 mg/kg/dose as necessary to achieve maintenance of sinus rhythm up to the maximum dose. **IV (only to be used in ICU setting and in the presence of paediatric electrophyiologist)**: 2 mg/kg over at least 10 minutes.
Dose adjustment	No information.
Maximum dose	8 mg/kg/day
Total cumulative dose	
Route	Oral [recommended route] IV **(only in ICU setting and in the presence of paediatric electrophyiologist)**
Preparation	**IV preparation** Draw up 1mL (10mg of flecainide) and add 9mL of glucose 5% to make 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 of the drug. **IV:** Infusion over at least 10 minutes. Patient 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.

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	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	Concurrent use of flecainide with drugs prolonging QT interval can lead to significant increase in QT interval. Examples of drugs prolonging QT interval: amiodarone, azithromycin, chloral hydrate, ciprofloxacin, cisapride, clarithromycin, digoxin, erythromycin, fluconazole, hydrochlorothiazide, ketoconazole, octreotide, propranolol, sodium phosphate, vasopressin, verapamil.
Adverse reactions	**Flecainide has been associated with life threatening ventricular arrhythmias. Use with extreme caution, preferably after other antiarrhythmic drugs have been tried or considered inappropriate.** **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 25ºC. Oral suspension compounded by Pharmacy stable for up to 60 days.
Storage	
Excipients	Silicified microcrystalline cellulose, croscarmellose sodium, maize starch, magnesium stearate.
Special comments	
Evidence	**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] 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 typically used as a second-line agent because of its arrhythmogenic potential. It has been used in infants with re-entrant supraventricular tachycardia including Wolff-Parkinson-White syndrome, focal atrial tachycardia and permanent junctional reciprocating tachycardia (case reports). It carries the risk of 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] **Pharmacokinetics:** Flecainide is cleared via hepatic biotransformation and renal excretion. Infants < 1 year of age had a mean $t_{½}$ of 11–12 hour; children aged 1 to 12 years had a $t_{½}$ of 8 hours. Dosing schedules based on mg/m^2 correlated better with plasma flecainide concentrations than did dosing based on mg/kg.[8,9] Oral bioavailability in adults reported to be 78–100%.
Practice points	
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