FLECAINIDE

Read in conjunction with Disclaimer

HIGH RISK Medication

Although flecainide may be effective in supraventricular arrhythmias in patients with structural heart disease, its use 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.

Formulary: Highly Restricted Requires cardiologist approval before commencing	
5 mg/mL Oral Suspension: Special Access Scheme (SAS): Category A	
Presentation	**Oral suspension: PCH:** 25 mg/5 mL = **5 mg/mL** (SAS) **KEMH: 2 mg/mL** (prepared in pharmacy) **Ampoule:** 150 mg/15 mL = **10 mg/mL**
Class	Membrane stabilising antiarrhythmic agent
Indication	Supression and prevention of ventricular arrhythmias and supraventricular tachycardia • Second-line agent where tachycardia has been resistant to first-line agents

Special Considerations	• Correct pre-existing hypokalemia or hyperkalemia before administration
	• Use with caution in renal and hepatic impairment
	• Use with caution in patients with congenital heart disease – increased potential for pro-arrhythmic effects
	• Use with caution in patients with conduction system disease:
	  • Right bundle branch block (when associated with a left hemiblock) without pacemaker
	  • Second or third degree heart block without pacemaker
	  • Sick sinus syndrome
	
	Contraindications:
	• Cardiogenic shock
	• Hypersensitivity to flecainide or any component of the formulation
	• Reduced left ventricular ejection fraction.

Compatibility	**Fluids:** Glucose 5% **Y-site:** At 2 mg/mL and 10 mg/mL of flecainide: insulin (Novorapid®)
Incompatibility	**Fluids:** Sodium chloride 0.9%, alkaline solutions **Y-site:** No information for compatibility with other medications, avoid combination if possible and contact pharmacy for further advice.
Monitoring	• ECG, blood pressure, pulse – in consultation with cardiologist. • Renal function. • Therapeutic drug monitoring (see below).

Therapeutic Drug Monitoring	• Periodic serum concentrations 3 to 5 days after initiation and following any dose change. • Infant formula and milk reduces absorption of flecainide – monitor plasma trough flecainide levels with major changes in dietary milk intake. **Time to reach steady state** – 3 to 5 days **Reference Range:** Therapeutic trough plasma level 0.2 to 1 mg/L **Sampling time** – prior to next dose
Interactions	• Flecainidine may increase the levels and effects of: digoxin, domperidone • The levels/effects of flecainidine may be increased by: amiodarone, sodium bicarbonate • Flecainide interacts with a number of medications – consult pharmacist for further advice • Caution when administering with other medications that prolong QT interval
Side effects	**Common:** New or worsened arrhythmia, bradycardia, photopsia, dyspnoea, vomiting, nausea, diarrhoea, fatigue
	Serious: Cardiac arrest, cardiac dysrhythmia, cardiogenic shock, abnormal electrocardiogram, heart block, heart failure, prolonged QT interval, sinus node dysfunction, torsades de pointes, ventricular fibrillation, ventricular tachycardia
Storage & Stability	**Oral Suspension (5 mg/mL SAS):** Store at room temperature, below 25°C. DO NOT refrigerate as crystallisation may occur. **Oral Suspension (2 mg/mL):** Store at room temperature. **Ampoule:** Store at room temperature, below 30°C. Protect from light.
Comments	SAS notification required for use of oral suspension at PCH

ORAL

Presentation (for oral use)	**Oral Suspension:** **PCH:** 25 mg/5 mL = **5 mg/mL** (SAS) **KEMH: 2 mg/mL** (prepared in pharmacy)
Dosage	***Consult Cardiologist before prescribing*** Initially 1 to 2 mg/kg/dose every 12 hours **Maximum dose:** 4 mg/kg/dose every 12 hours
	Dose adjustment • Adjust dose according to response and serum concentration • Optimal effect may take 2 to 3 days of therapy to achieve, avoid increasing the dose until steady state is achieved (3 to 5 days) • **Renal impairment:** Dose adjustment and/or therapeutic drug concentration monitoring may be required. Discuss with paediatric cardiologist. • **Hepatic impairment:** Use with caution in significant hepatic impairment. Elimination from the plasma may be slower in patients with hepatic impairment.
Preparation	**PCH** – Use SAS formulation **KEMH** – Use suspension prepared in Pharmacy *If solution not available – prepare the following solution using 100 mg flecainide tablets:* • Disperse ONE flecainide tablet (100 mg) in **50 mL** of water for injection • Tablet will disperse within 1 to 2 minutes • Concentration is 100 mg/50 mL = **2 mg/mL** • Discard any unused solution immediately
Administration	• Shake oral suspension well before use • Draw prescribed dose into oral/enteral syringe • Can be given Oral/OGT/NGT • Separate from feeds as milk and formula may reduce absorption of flecainide

INTRAVENOUS INFUSION

Presentation (for IV use)	**Ampoule:** 150 mg/15 mL = **10 mg/mL**
Dosage	INTRAVENOUS FLECAINIDE IS **RARELY INDICATED**. **Prescription and administration <u>must</u> only occur under the direction of a cardiologist. The intended route <u>must</u> be clearly communicated and documented in the medical record.** 0.5 mg/kg/dose. Maximum dose of 2 mg/kg may be given. **Dose adjustment** • **Renal impairment:** Dose adjustment may be required. Discuss with cardiologist. • **Hepatic impairment:** Use with caution in significant hepatic impairment.
Preparation	**Dilution:** • Draw up **1 mL** (10 mg of flecainide) and add **9 mL** of glucose 5% to make a final volume of 10 mL • *Concentration is now equal to **1 mg/mL***
Administration	**At PCH:** A cardiologist, anaesthetist, neonatologist or paediatric critical care consultant **MUST BE PRESENT** during intravenous administration. **At KEMH:** A cardiologist **MUST BE PRESENT** during intravenous administration. • Infuse via syringe driver over at least 10 minutes. • **Patient needs to be monitored very closely with the potential for an acute deterioration.**

Related Policies, Procedures, and Guidelines

CAHS Clinical Practice Guidelines:

Cardiac Arrhythmias

Cardiac Arrest and Arrhythmias in NICU: Treatment Algorithms

WNHS Pharmaceutical and Medicines Management Guidelines:

High Risk Medicines

References

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