MONOGRAPH

Flecainide

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

⚠ HIGH RISK MEDICINE ⚠

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Antiarrhythmic[1]

Flecainide is a High Risk Medicine.

INDICATIONS AND RESTRICTIONS

Flecainide is restricted for use under the direction of a Cardiologist.

Flecainide solution is a special access scheme (SAS) product. SAS application(s) must be completed in accordance with the TGA regulations.

- Suppression and prevention of life-threatening ventricular arrhythmias refractory to other treatment (e.g. sustained ventricular tachycardia)[2-4]
- Suppression and prevention of supraventricular arrhythmias (e.g. Wolff-Parkinson-White syndrome, atrial fibrillation/flutter)[2-4]
- Maintenance of sinus rhythm after cardioversion[1]

CONTRAINDICATIONS

- Hypersensitivity to flecainide or any component of the formulation.[2, 3, 5]
- Second- or third-degree heart block without a pacemaker.[2, 3, 5]
- Right bundle branch block (when associated with a left hemiblock) without a pacemaker.[3, 5]
- Cardiogenic shock/abnormal left ventricular function or history of myocardial infarction.[2, 3, 5]
- Concurrent treatment with disopyramide.[1]

PRECAUTIONS

- Concurrent use with other anti-arrhythmic drugs – May cause a proarrhythmic effect[2]
- Electrolyte disturbances (e.g. hypokalaemia, hyperkalaemia, hypomagnesaemia) – May increase the risk of arrythmias. Correct before starting treatment if possible. [1, 3]
- Sick Sinus Syndrome – May increase the risk of significant bradycardia. Use with extreme caution and only if pacing facilities are available[1]
- Heart failure – may worsen with flecainide use[1]
- Paediatric patients – May experience a disproportionate increase in plasma concentrations following small changes in dose.[6]
- Patients with atrial flutter after surgery and patients with structural heart disease – May be at an increased risk of potentially fatal arrhythmias. Use with extreme caution after other antiarrhythmic agents have been tried or considered inappropriate. [1-3, 5, 6]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 150 mg / 15 mL ampoule
- 50 mg tablet
- 5 mg/ mL solution (SAS product)

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Oral:

- ≥ 4 weeks – 11 years: Initially 1 – 3 mg/kg/day in two to three divided doses[4]
  - Titrate dose every 4 days to a maximum of 8 mg/kg/day[6]
  - Usual maintenance range: 3 – 6 mg/kg/day[6]
- 12 – 17 years: Initially 50 – 100 mg twice daily[4]
  - Titrate up to a maximum dose of 400 mg daily

Most patients will require less than 300 mg daily.[4]

Intravenous:

Intravenous Flecainide is rarely indicated.
Prescribing and administration must only occur under the direction of a Consultant Cardiologist

- Intravenous administration should only be used when the rapid control of arrythmias is required in an emergency. Oral therapy to be substituted as soon as possible.
    - At PCH, a Cardiologist, Anaesthetist, Neonatologist or Paediatric Critical Care Consultant must be present when IV flecainide is administered to a neonate.
- I> 4 weeks – 17 years: 0.5 – 2 mg/kg[11] (to a maximum of 150 mg)

Renal impairment:

- Reduce dose by 25–50% if eGFR less than 35 mL/minute/1.73 m^2 [4]
- eGFR calculator

Hepatic impairment:

- Avoid or reduce dose in severe impairment[4]

RECONSTITUTION & ADMINISTRATION

Oral Administration:

- Separate doses from milk, infant formula and dairy products as absorption of flecainide may be reduced.[3, 4]
    - If not possible (during times of reduced milk consumption such as illness or weaning), monitor closely and reduce dose if required.[3]

Intravenous Administration:

IV Flecainide must only be administered in a critical care setting (i.e. Neonatal Intensive Care Unit (NICU), Paediatric Critical Care (PCC), Theatre or Emergency Department)

- Intravenous Injection: Inject all doses over at least 10 minutes[7]

For all doses less than 2 mg the flecainide 150 mg/15 mL ampoule must be first diluted to allow for the accurate measurement of the dose.

The following dilution should be used:

Withdraw 1 mL (10 mg) of Flecainide and make up to 10 mL total volume with Glucose 5%

Concentration now equal to 1 mg/mL

    - Dilute dose to a suitable volume with a compatible fluid to allow for administration via an infusion pump or injected undiluted (if volume is sufficient).

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids: Glucose 5%[8]

Compatible at Y-site: At 2 mg/mL and 10 mg/mL of Flecainide: Insulin (Novorapid®)[8]

INCOMPATIBLE drugs: No information[8]

MONITORING

- ECG, blood pressure and pulse[3, 6]
- Renal function[6]

Symptoms of toxicity:

- Non-cardiac manifestations: nausea, vomiting, seizures[5]
- Cardiotoxicity: bradycardia, hypotension, ventricular tachyarrhythmias, heart block and asystole[5]

Therapeutic drug monitoring:

- Therapeutic drug monitoring is not routinely performed at PCH.
- References indicate a therapeutic trough plasma level of 0.2 – 1 mg/L; paediatric patients usually respond to the lower end of the range (0.2 – 0.5 mg/L)[5, 6]

ADVERSE EFFECTS

Common: exacerbation of arrhythmias, nausea, vomiting, diarrhoea, constipation, headache, dizziness, tinnitus, visual disturbances, fatigue, tremor, nervousness, paraesthesia, ataxia, dyspnoea, flushing, increased sweating, rash[1]

Infrequent: bradyarrhythmia's, heart block (second- or third-degree), hallucinations, amnesia, confusion[1]

Rare: cardiac arrest, sudden death, hepatic dysfunction[1]

STORAGE

Ampoule: Store below 30ºC. Protect from light[2]

Tablets: Store below 30ºC[2]

Oral Solution: Store below 25ºC. Do not refrigerate or freeze (crystallisation may occur)[9]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **Flecainide**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

High Risk Medicines (CAHS Policy Manual)

References

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