SOTALOL

Read in conjunction with Disclaimer

HIGH RISK Medication

Formulary: Highly Restricted Requires cardiologist or neonatologist approval **before** commencing.	
Special Access Scheme (SAS): Category A – 40 mg/4 mL ampoule	
Presentation	**Suspension:** 10 mg/mL (KEMH pharmacy) **Tablet:** 80 mg **Ampoule:** 40 mg/4 mL (10 mg/mL) - SAS
Classification	Non-cardioselective beta adrenergic blocking agent.
Indication	Treatment of supraventricular and ventricular tachyarrhythmias.
Special Considerations	• Sotolol should not be used when there is shock (cardiogenic or hypovolaemia), congestive cardiac failure, sinus bradycardia, heart block, congenital or acquired long QT syndromes, hypokalaemia or hypomagnesaemia. • During intravenous administration, resuscitation equipment must be accessible. Atropine must be available for profound bradycardia.
Monitoring	• Perform a 12 lead ECG before and after the first dose to assess for any increase in QT interval from baseline. To be performed with the initial dose and after any increases in dose. Consult paediatric cardiology for advise. • For initiation of therapy and for intravenous treatment, infant should be on cardiorespiratory monitor. • Monitor electrolytes, especially potassium and magnesium. Normalise levels prior to initiation and during use.
Compatibility	**Fluids:** Sodium chloride 0.9%, glucose 5%
Incompatibility	**Y-site:** There is limited information regarding Y-site compatibility of sotalol with other medications. Avoid combination if possible and contact pharmacy for further advice if required.
Interactions	• Use caution when using sotalol with other medications that can prolong the QT interval and drugs with antiarrhythmic properties. • Concomitant use of sotalol and diuretics may increase the cardiotoxicity.
Side Effects	• Dyspnoea, fatigue, dizziness, headache, fever, excessive bradycardia and/or hypotension. Usually transient and subside when sotalol dose is reduced. • Sotalol may be proarrhythmic with prolongation of QT interval. • Rarely has been associated with torsades de pointes.
Storage & Stability	**Ampoules and tablet:** Store at room temperature, below 25°C. **Oral suspension:** Refrigerate, store at 2 to 8°C.

ORAL

Presentation (for oral use)	**Suspension:** 10 mg/mL (KEMH pharmacy) **Tablet:** 80 mg
Dosage	*Preferred route* **Initial dose:** 1 mg/kg/dose every 12 hours. Gradually increase as needed every 3 to 5 days until stable rhythm is maintained. **Maximum dose:** 4 mg/kg/dose every 12 hours.
	Renal impairment: Sotalol can accumulate in renal impairment; increase dosing interval; seek specialist advice in severe impairment.
Preparation	**Use suspension made by pharmacy.** *If suspension not available – prepare the following solution using sotalol 80 mg tablet:* • Disperse one sotalol tablet (80 mg) in 16 mL of water. • Tablet may take vigorous shaking for 5 to 10 minutes to disperse. • Concentration is **5 mg/mL**. • Discard any unused solution.
Administration	• Shake well before use. • Draw prescribed dose into oral/enteral syringe. • Can be given Oral/OGT/NGT. • Give on an empty stomach, half an hour before a feed or 2 hours after.

INTRAVENOUS

Presentation (for IV use)	**Ampoule:** 40 mg/4 mL (10 mg/mL) – SAS ***Note:*** *IV sotalol is accessed via the Special Access Scheme and is not stocked at KEMH or PCH. Consider another medication or route of administration if required urgently.*
Dosage	**Note:** During intravenous administration, resuscitation equipment must be accessible. Atropine must be available for profound bradycardia. 0.5 to 1.5 mg/kg/dose every 12 hours.
	Renal impairment: Sotalol can accumulate in renal impairment; increase dosing interval; seek specialist advice in severe impairment.
Preparation	**Dilution:** Take 1 mL (10 mg) of sotalol solution and dilute to 5 mL with compatible diluent. Concentration = 10 mg/5 mL = 2 mg/mL
Administration	**IV infusion:** • Infuse via syringe driver over at least 10 minutes. • The cannula should be flushed with sodium chloride 0.9% pre- and post-administration of sotalol. • During intravenous administration, resuscitation equipment must be accessible. Atropine must be available for profound bradycardia.

Related Policies, Procedures, and Guidelines

HDWA Mandatory Policies:

MP 0131/20: WA High Risk Medication Policy

CAHS Neonatology Clinical Practice Guidelines:

Cardiac: Arrhythmias

Pharmaceutical and Medicines Management Guidelines:

CAHS Neonatology – Medication Administration Guideline

High Risk Medicines

WNHS Cold Chain Management for Medications and Vaccines

CAHS Medication Refrigerators and Freezers

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Document history

Keywords	Sotalol, Sotacor, beta-blocker, SVT, arrhythmias				
Abbreviations	IV: intravenous, KEMH: King Edward Memorial Hospital, PCH: Perth Children's Hospital				
Document Owner:	Chief Pharmacist				
Author/ Reviewer	KEMH & PCH Pharmacy/Neonatology Directorate				
Version Info:	V4.0 – Full review				
Date First Issued:	01/2001	Last Reviewed:	25/09/2025	Review Date:	25/09/2030
Endorsed by:	Neonatal Directorate Management Group			Date:	28/10/2025
NSQHS Standards Applicable:	☒ Std 1: Clinical Governance		☒ Std 4: Medication Safety		
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