

Alert	Sotalol can prolong QTc interval. A 12-lead ECG is to be done before and after the commencement of sotalol (see adverse reactions section).
Indication	For the maintenance of sinus rhythm in conditions such as supraventricular tachycardia (SVT) and atrial tachycardia after consultation with cardiologist.
Action	Nonselective beta-blocking agent with class III effects at higher serum concentrations.
Drug Type	Antiarrhythmic.
Trade Name	IV: Sotacor Concentrate. Oral: Suspension prepared by pharmacy.
Presentation	IV: 40 mg/4 mL. Oral: 5 mg/mL suspension.
Dosage / Interval	If possible, treatment with the oral preparation is preferred. Oral: Starting dose 1 mg/kg/dose 12 hourly. Gradually increase every 3 to 4 days until adequate sinus rhythm is maintained. Doses greater than 4 mg/kg/day are best administered 8 hourly. IV: 0.5–1.5 mg/kg/dose 12 hourly by slow IV infusion over 10 minutes.
Maximum daily dose	4 mg/kg/day in neonatal period and 6 mg/kg/day beyond neonatal period. If dosing higher than this is being considered, consult a paediatric cardiologist.
Route	Oral IV
Preparation/Dilution	Oral: 5 mg/mL suspension (prepared by pharmacy). IV: Draw up 1 mL of sotalol (10 mg) and add 4 mL sodium chloride 0.9% to make a final volume of 5 mL solution with a concentration of 2 mg/mL.
Administration	IV: Via peripheral or central cannula over 10 minutes. The cannula should be flushed with sodium chloride 0.9% pre- and post-administration of sotalol. Oral: Preferably administered on an empty stomach; at least 30 minutes before feeding.
Monitoring	Perform a 12 lead ECG before and after the first dose to assess for any increase in QTc interval from baseline. To be performed with the initial dose and after any increases in dose. For initiation of therapy and for intravenous treatment, infant should be on cardiorespiratory monitor. Monitor electrolytes, especially potassium and magnesium.
Contraindications	Bronchospasm/asthma. Allergic disorders which suggest a predisposition to bronchospasm. Right ventricular failure secondary to pulmonary hypertension. Significant right ventricular hypertrophy. Sinus bradycardia. Second and third degree atrioventricular block or sick sinus syndrome unless a functioning pacemaker is present. Shock, including cardiogenic and hypovolaemic shock. Uncontrolled congestive heart failure. Severe renal impairment. Congenital or acquired long QT syndromes. Hypersensitivity to sotalol hydrochloride or the excipients. Anaesthesia that produces myocardial depression.
Precautions	During intravenous administration, have the resuscitation equipment nearby and atropine should be available for profound bradycardia. Atropine 10–30 microgram/kg/dose IV over 1 minute. Dose may be repeated every 10–15 minutes to achieve desired effect, with a maximum total dose of 40 microgram/kg. No antiarrhythmic drug has been shown to reduce the incidence of sudden death in patients with supraventricular or asymptomatic ventricular arrhythmias. Sotalol is proarrhythmic in some situations and at higher doses. Sotalol is renally excreted – use with caution in patients with renal impairment.
Drug Interactions	Sotalol clearance is reduced by alcohol. Other interactions include: Insulin and oral hypoglycaemics (hypo- and hyperglycaemia); calcium channel blockers (hypotension, bradycardia, heart failure); clonidine (hypertension); drugs that prolong

	<p>the Qtc interval (quinolone antibiotics).</p> <p>Sotalol interactions have been reported with other antiarrhythmics: Class IA agents, disopyramide and quinidine; class IB, tocainide, mexiletine and lignocaine; class IC, flecainide and propafenone; class III, amiodarone; and class IV antiarrhythmic agents. Concomitant use of sotalol with these agents and with other beta-blocking drugs is not recommended.</p> <p>Concomitant use of sotalol and diuretics may increase the cardiotoxicity.</p>
Adverse Reactions	<p>Sotalol is usually well tolerated. The most frequent adverse events arise from its beta-blockade properties. Adverse events are usually transient in nature and include dyspnoea, fatigue, dizziness, headache, fever, excessive bradycardia and/or hypotension. These side effects usually disappear when the dose is reduced.</p> <p>Sotalol may be proarrhythmic with prolongation of Qtc interval.</p> <p>Uncommonly sotalol may be associated with torsades de pointes: Cease medication; correct electrolyte abnormalities; give magnesium 0.1–0.2 mmol/kg = 25–50 mg/kg IV.¹</p>
Compatibility	<p>Fluids: Glucose 5% and sodium chloride 0.9%</p> <p>Y-site: No information. Do not mix with other drugs.</p>
Incompatibility	Fluids and drugs: No information.
Stability	Diluted solution: Stable at room temperature for 24 hours. Discard any remaining solution after use.
Storage	<p>Ampoules: Store at 25°C.</p> <p>Oral suspension prepared by pharmacy: Refrigerate, store at 2–8°C</p>
Evidence summary	As per NMF Consensus Group. Refer to reference manual or electronic version.
References	As per NMF Consensus Group. Refer to reference manual or electronic version.

Original version Date: 18/07/2016	Author: Neonatal Medicines Formulary Consensus Group
Current Version number: 1	Current Version Date: 18/07/2016
Risk Rating: Medium	Due for Review: 27/09/2019
Approval by: JHCHCQ&PCC	Approval Date: 27/09/2016