**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.
### Evidence summary

**Efficacy:**

- **ARC (ANZCOR) treatment recommendations for supraventricular tachycardia:** Sotalol is not considered as a treatment option for acute treatment of infants with SVT. Adenosine is the drug of choice. Alternative drugs are procainamide, [Class B; LOE IV] digoxin, a beta blocker or a calcium channel blocker (calcium channel blockers should not be used to treat SVT in infants).1
- **eTG Complete (Therapeutic Guidelines November 2015):** There is no infant recommendation. Sotalol is a treatment option for:
  - Paroxysmal supraventricular tachycardia (oral);
  - Nonsustained ventricular tachycardia if associated with symptoms or haemodynamic compromise (oral);
  - Sustained ventricular tachycardia including if haemodynamically unstable (IV) and for ongoing treatment (oral).

- **2015 ACC/AHA/HRS guidelines:** There is no infant recommendation. Sotalol may be reasonable for ongoing management in patients with symptomatic SVT who are not candidates for, or prefer not to undergo, catheter ablation. (LOE II, GOR B)

- **Sotalol for paroxysmal SVT:** In a single RCT in adults, sotalol was shown to be effective in reducing SVT recurrence and time to recurrence.2 In case series in neonates and children, paroxysmal SVT was completely or partially controlled in 80–90% of patients.2–6 (LOE IV GOR C) Sotalol has been reported in combination with flecainide for treatment of refractory SVT in children < 1 year of age.6 (LOE IV, GOR C)

- **Pharmacokinetics:** Sotalol is mainly excreted unchanged, renally.7 Sotalol is rapidly absorbed, with mean peak concentrations 2 to 3 hours after administration; half-life 7 to 9 hours.8 Neonates have variable oral absorption of sotalol resulting in two-fold variation in plasma concentrations compared to children.9 Neonates show a higher sensitivity toward QTc interval prolongation compared with older patients.7 QTc and RR interval prolongation are linearly related to the sotalol plasma concentration.7

**Safety:**

Side effects of sotalol reported in infants include prolongation of QTc interval, bradycardia/pauses, and torsades de pointes.

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ANZCOR treatment recommendations for polymorphic ventricular tachycardia (torsades de pointes):
Cease medication associated with cause; correct electrolyte abnormalities; give magnesium 0.1–0.2 mmol/kg = 25–50 mg/kg IV.1

Overdose guideline: A child ingesting > 4 mg/kg of sotalol as a single dose requires emergency department evaluation.10, 11

References

Original version Date: 18/07/2016
Current Version number: 1
Current Version Date: 18/07/2016
Risk Rating: High
Due for Review: 18/07/2018
Approval by: As per Local policy
Approval Date: 4/8/16

Neonatal Medicines Formulary Consensus Group

Sotalol

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This RHW document is a modification of Neomed version. Dosage schedules remain the same. However, information on the commercial preparations not used at RHW is deleted. The risk rating is modified as per the local health district policy.