Sotalol

Newborn use only

2021

Alert	Sotalol can prolong QTc interval. A 12-lead ECG is to be performed 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	Oral: Suspension prepared by pharmacy. IV: (1) Sotacor Concentrate, (2) Sotalol-Carinopharm – SAS product.
Presentation	Oral: 5 mg/mL suspension. IV: 40 mg/4 mL.
Dose	Treatment via the oral route 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.
Dose adjustment	Time to steady state increases with age and may be 1 week or longer in neonates.[13]
Maximum 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.
Total cumulative dose	
Route	Oral IV
Preparation	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. Oral: Preferably administered on an empty stomach; at least 30 minutes before feeding.
Monitoring	Perform a baseline 12-lead ECG before and after the first dose to assess for any increase in QTc interval. 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. Baseline serum creatinine. Blood pressure, heart rate, 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 resuscitation equipment nearby. 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 QTc interval. 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. Concomitant use of sotalol and diuretics may increase the cardiotoxicity.
Adverse reactions	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. Sotalol may be pro-arrhythmic with prolongation of QTc interval. 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]
Compatibility	Fluids[13]: Glucose 5% and sodium chloride 0.9% Y-site[13]: No information. Do not mix with other drugs.
Incompatibility	Fluids and drugs[13]: No information.
Stability	Diluted IV solution - stable at room temperature for 24 hours. Oral suspension: check with local Pharmacy.
Storage	Ampoules: Store below 25°C. Oral suspension prepared by pharmacy: Check with local Pharmacy.
Excipients	Oral: Dependent on local pharmacy compounding formula. IV SAS Sotalol-Carino product: Sodium chloride, acetic acid 99%, water for injections, sodium hydroxide solution 7.4%.
Special comments	
Evidence	**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); • Non-sustained 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.[3-6] (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.[5] 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. **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]
Practice points	
References	1. Australian Resuscitation C, New Zealand Resuscitation C. Management of specific dysrhythmias in paediatric advanced life support. ARC and NZRC Guideline 2010. Emergency medicine Australasia: EMA. 2011;23:409-11. 2. Wanless RS, Anderson K, Joy M, Joseph SP. Multicenter comparative study of the efficacy and safety of sotalol in the prophylactic treatment of patients with paroxysmal supraventricular tachyarrhythmias. American heart journal. 1997;133:441-6. 3. Celiker A, Ayabakan C, Ozer S, Ozme S. Sotalol in treatment of pediatric cardiac arrhythmias. Pediatrics international : official journal of the Japan Pediatric Society. 2001;43:624-30. 4. Knudson JD, Cannon BC, Kim JJ, Moffett BS. High-dose sotalol is safe and effective in neonates and infants with refractory supraventricular tachyarrhythmias. Pediatric cardiology. 2011;32:896-903. 5. Laer S, Elshoff JP, Meibohm B, Weil J, Mir TS, Zhang W, Hulpke-Wette M. Development of a safe and effective pediatric dosing regimen for sotalol based on population pharmacokinetics and pharmacodynamics in children with supraventricular tachycardia. Journal of the American College of Cardiology. 2005;46:1322-30. 6. Price JF, Kertesz NJ, Snyder CS, Friedman RA, Fenrich AL. Flecainide and sotalol: a new combination therapy for refractory supraventricular tachycardia in children <1 year of age. Journal of the American College of Cardiology. 2002;39:517-20. 7. Shi J, Ludden TM, Melikian AP, Gastonguay MR, Hinderling PH. Population pharmacokinetics and pharmacodynamics of sotalol in pediatric patients with supraventricular or ventricular tachyarrhythmia. Journal of pharmacokinetics and pharmacodynamics. 2001;28:555-75. 8. Saul JP, Schaffer MS, Karpawich PP, Erickson CC, Epstein MR, Melikian AP, Shi J, Karara AH, Cai B, Hinderling PH. Single-dose pharmacokinetics of sotalol in a pediatric population with supraventricular and/or ventricular tachyarrhythmia. Journal of clinical pharmacology. 2001;41:35-43. 9. Khalil F, Laer S. Physiologically based pharmacokinetic models in the prediction of oral drug exposure over the entire pediatric age range-sotalol as a model drug. The AAPS journal. 2014;16:226-39. 10. Hickey CN, Mycyk MB, Wahl MS. Can a poison center overdose guideline safely reduce pediatric emergency department visits for unintentional beta-blocker ingestions? American journal of therapeutics. 2012;19:346-50. 11. Wax PM, Erdman AR, Chyka PA, Keyes DC, Caravati EM, Booze L, Christianson G, Woolf A, Olson KR, Manoguerra AS, Scharman EJ, Troutman WG. beta-blocker ingestion: an evidence-based consensus guideline for out-of-hospital management. Clinical toxicology. 2005;43:131-46. 12. Australian Injectable Drugs Handbook. Accessed online on 18 May 2021. 13. Micromedex. Accessed online on 18 May 2021.

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