



SOTALOL IV
sotalol hydrochloride injection
10mL vial (15mg/mL)

**Intravenous rhythm control
for pediatric patients**



SOTALOL IV
sotalol hydrochloride injection
10mL vial (15mg/mL)

Flexible patient management with Sotalol IV
Sotalol offers benefits for pediatric drug therapy



FAST ONSET

Facilitates timely evaluation of therapeutic response to support clinical decision-making.



LINEAR KINETICS

Allows for predictable dosing, simplified dose adjustment, and smooth transition to oral therapy.



SHORT HALF-LIFE

Enables prompt discontinuation and transition to alternative treatment strategies.



INTRAVENOUS INFUSION

Offers controlled delivery and less variability in absorption compared to oral dosing alone.

Consider intravenous sotalol for your pediatric patients.

Sotalol is an antiarrhythmic indicated for:

- The maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter (AFIB/AFL)) in adults and pediatric patients with highly symptomatic AFIB/AFL who are currently in sinus rhythm.
Limitations of use: Avoid use in patients with minimally symptomatic or easily reversible AFIB/AFL.
- The treatment of documented, life-threatening ventricular arrhythmias, such as sustained ventricular tachycardia in adult and pediatric patients.
Limitations of use: Sotalol has not been shown to enhance survival in patients with life-threatening ventricular arrhythmias.



Same molecule, different formulation

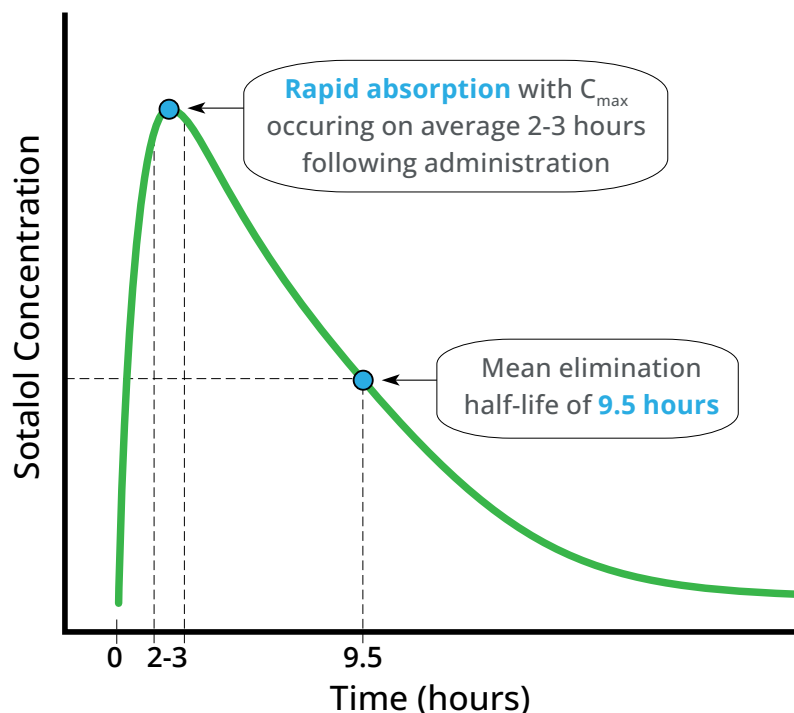
Sotalol IV offers the **same active molecule as oral sotalol** but in an intravenously infused formulation. Sotalol IV **bypasses the GI tract**, supporting more predictable exposure and use in patients with limited oral or GI tolerance. In addition, the **rapid onset** of Sotalol IV allows for faster assessment of therapeutic response than oral dosing alone.

Sotalol's pharmacokinetics in children¹

The combined analysis of two unblinded, multicenter trials of oral sotalol with 59 children, aged between 3 days and 12 years, showed the **pharmacokinetics of sotalol to be first order**, or that a constant proportion is eliminated over time.¹

BSA was the most important covariate and more relevant than age for the pharmacokinetics of sotalol. The smallest pediatric patients exhibited a greater drug exposure than the larger pediatric patients who showed a uniform drug concentration profile.¹

Oral sotalol concentration over time¹



- **The short mean elimination half-life of sotalol** offers clinicians greater control, enabling rapid discontinuation and seamless transition to other care options when needed.
- **Sotalol's linear pharmacokinetics** provide flexible dosing and facilitate smooth IV-to-oral transition.



The Class III electrophysiologic and beta-blocking effects, the pharmacokinetics, and the relationship between the effects and drug concentrations have been evaluated in pediatric patients between 3 days and 12 years of age.¹

Get acquainted with Sotalol IV.

Learn why intravenous sotalol could be right for your pediatric health practice.

sotaloliv.com/go/pediatrics



✉ customerservice@altathera.com

☎ 1-312-445-8900

WARNING: LIFE THREATENING PROARRHYTHMIA

Sotalol can cause life threatening ventricular tachycardia associated with QT interval prolongation. To minimize the risk of drug induced arrhythmia, initiate or uptitrate intravenous sotalol in a facility that can provide continuous electrocardiographic monitoring and cardiac resuscitation [see Dosage and Administration (2.3) and Warnings and Precautions (5.1)]

Do not initiate intravenous sotalol therapy if the baseline QTc is longer than 450 ms. If the QTc prolongs to 500 ms or greater, reduce the dose or discontinue.



SOTALOL IV
sotalol hydrochloride injection
10mL vial (15mg/mL)



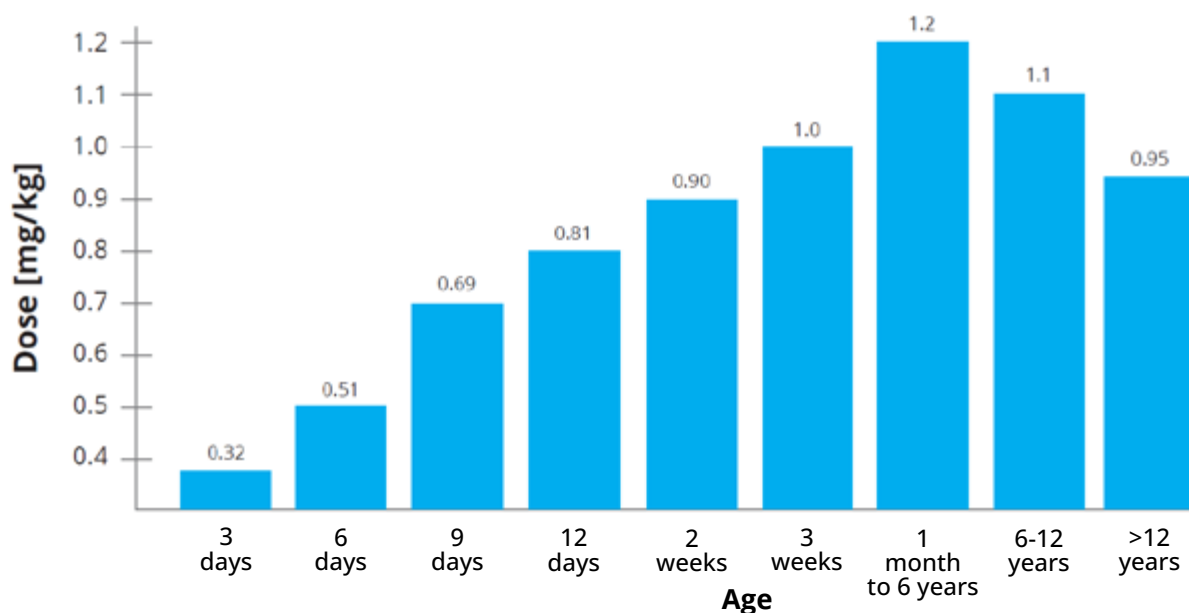
Considerations & Dosing Information

- **Toxicity:** Sotalol is hydrophilic and does not bind to plasma proteins. It crosses the blood brain barrier poorly, and is not metabolized.¹
- **Labs:** Potassium and magnesium should be measured and normalized prior to administration.¹

Close inpatient monitoring is recommended until steady state drug levels are achieved.¹

Proarrhythmic effects of sotalol in pediatric patients included increased ventricular ectopy and exacerbation of bradycardia, the latter predominantly in patients with sinus node dysfunction following surgery for congenital cardiac defects

Suggested starting doses [mg/kg] in children with normal renal function.¹

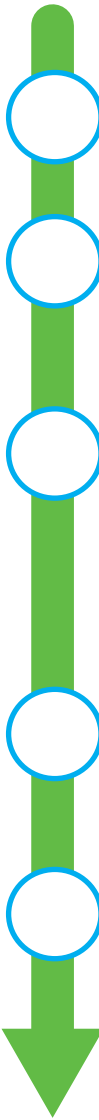


Side effects of other sotalol-containing drug products in pediatric patients are those typical of a beta blocking agent, and led to discontinuation of drug in 3-6% of patients.¹

- As in adults, the Class III antiarrhythmic action of sotalol in pediatric patients is associated with a significant proarrhythmic potential.
- In pediatric patients, the incidence of proarrhythmic side effects of sotalol varies from 0 to 22%; and the smallest pediatric patients tended to exhibit greater QTC-prolongation.

Contact us:  customerservice@altathera.com

 1-312-445-8900



Sotalol is a **trusted antiarrhythmic**.

Oral sotalol has been studied and used in pediatric patients for decades; Sotalol IV contains the **same active molecule**.

1992

Oral sotalol first approved by US FDA.²

2009

Intravenous sotalol first approved by FDA for use in patients unable to take oral formulation.³

2020

Intravenous sotalol receives indications and recommended dosing from FDA for the initiation and uptitration of sotalol therapy in adults with symptomatic atrial fibrillation, atrial flutter, and life-threatening ventricular tachycardia.⁴

2025

Intravenous formulation receives expanded indications from FDA specifying approval for pediatric use.¹

Today

Intravenous sotalol is used under careful monitoring at pediatric institutions across the country for the treatment of pediatric arrhythmias such as atrial flutter.

A Small & Critical Patient Population

Our Commitment to Pediatrics

AltaThera's work is driven by a commitment to bringing specialized solutions to under-served patient populations and complex therapeutic areas. Our team of doctors, nurses, and trained professionals is prepared to help find you the answers you need, so that you can provide the best care possible to your patients.

WARNING: LIFE THREATENING PROARRHYTHMIA

Sotalol can cause life threatening ventricular tachycardia associated with QT interval prolongation. To minimize the risk of drug induced arrhythmia, initiate or uptitrate intravenous sotalol in a facility that can provide continuous electrocardiographic monitoring and cardiac resuscitation [see Dosage and Administration (2.3) and Warnings and Precautions (5.1)]

Do not initiate intravenous sotalol therapy if the baseline QTc is longer than 450 ms. If the QTc prolongs to 500 ms or greater, reduce the dose or discontinue.

Highlights of Prescribing Information

Indications, Boxed Warning, and Important Safety Information

Sotalol is an antiarrhythmic indicated for:

- the treatment of documented, life-threatening ventricular arrhythmias, such as sustained ventricular tachycardia in adult and pediatric patients.
Limitations of Use: Sotalol has not been shown to enhance survival in patients with life-threatening ventricular arrhythmias.
- the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter (AFIB/AFL)) in adults and pediatric patients with highly symptomatic AFIB/AFL who are currently in sinus rhythm.
Limitations of Use: Because sotalol can cause life-threatening ventricular arrhythmias, reserve its use for patients in whom AFIB/AFL is highly symptomatic.

Important Safety Information

WARNING: LIFE THREATENING PROARRHYTHMIA

Sotalol can cause life threatening ventricular tachycardia associated with QT interval prolongation. To minimize the risk of drug induced arrhythmia, initiate or up-titrate intravenous sotalol in a facility that can provide continuous electrocardiographic monitoring and cardiac resuscitation [see Dosage and Administration (2.3) and Warnings and Precautions (5.1)]

Do not initiate intravenous sotalol therapy if the baseline QTc is longer than 450 ms. If the QTc prolongs to 500 ms or greater, reduce the dose or discontinue.

CONTRAINDICATIONS

- Bradyarrhythmia, sick sinus syndrome or 2nd or 3rd degree atrioventricular (AV) block without a pacemaker (4)
- Congenital or acquired long QT syndrome (4)
- Cardiogenic shock or decompensated heart failure (4)
- Serum potassium < 4mEq (4)
- Bronchial asthma or related bronchospastic conditions (4)
- Hypersensitivity to sotalol (4)

WARNINGS AND PRECAUTIONS

- Risk of life-threatening ventricular arrhythmias, particularly torsade de pointes (TdP). The risk of TdP can be reduced by adjustment of the sotalol dose according to renal function and by monitoring the ECG for excessive increases in QTc. (5.1)
- Bradyarrhythmia, AV block, sick sinus syndrome. Sotalol-induced bradycardia increases the risk of Torsade de Pointe, particularly following cardioversion. In general, sotalol is not recommended in patients with sick sinus syndrome associated with symptomatic arrhythmias, because it may cause sinus bradycardia, sinus pauses, or sinus arrest. (5.2, 5.3)
- Negative inotropy: hypotension, heart failure. Monitor hemodynamics during administration. New onset or worsening heart failure may occur during initiation or up-titration of sotalol because of its beta-blocking effects. Monitor for signs and symptoms of heart failure and discontinue treatment if symptoms occur. (5.4, 5.5)
- Bronchospasm. Avoid sotalol use in patients with bronchospastic diseases. If sotalol is required, use the smallest effective dose. (5.6)
- Hypoglycemia. Beta-blockade may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Diabetic patients may experience elevated blood glucose levels and increased insulin requirements. (5.7)
- Thyroid Abnormalities. Avoid abrupt withdrawal of beta-blockade which might be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Beta-blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. (5.8)
- Anaphylaxis. While taking beta-blockers, patients with a history of anaphylactic reaction to a variety of allergens may have a more severe reaction on repeated challenge, either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat the allergic reaction. (5.9)
- Anesthesia. The impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures. (5.10)

ADVERSE REACTIONS

- Proarrhythmia (5.1, 5.2)
- Negative inotropy (5.3, 5.4)

Adverse reactions related to sotalol use are those which are typical of its Class II (beta-blocking) and Class III (cardiac action potential duration prolongation) effects. The common documented beta-blocking adverse reactions (bradycardia, dyspnea, and fatigue) and Class III effects (QT interval prolongation) are dose related.

To report SUSPECTED ADVERSE REACTIONS, contact AltaThera Pharmaceuticals LLC at 1-800-524-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Antiarrhythmic and other QT-prolonging Drugs – Concomitant use is not recommended due to the risk of additive QTc prolongation. (7.1)
- Negative chronotropes – Concomitant use with digitalis glycosides and beta-blockers increases the risk of bradycardia. (7.2)
- Calcium blocking drugs – Sotalol and calcium blocking drugs can be expected to have additive effects slowing atrioventricular conduction, ventricular function, and blood pressure. (7.3)
- Catecholamine-Depleting Agents – Concomitant use with catecholamine-depleting drugs may produce an excessive reduction of resting sympathetic nervous tone. Monitor for hypotension and marked bradycardia which may produce syncope (7.4)
- Insulin and Oral Antidiabetics – Hyperglycemia may occur, and the dosage of insulin or antidiabetic drugs may require adjustment. Symptoms of hypoglycemia may be masked. (7.5)
- Beta-2-Receptor Stimulants – Beta-agonists may have to be administered in increased dosages when used concomitantly with sotalol. (7.6)
- Clonidine – Concomitant use with sotalol increases the risk of bradycardia. (7.7)
- Drug/Laboratory Test Interactions – The presence of sotalol in the urine may result in falsely elevated levels of urinary metanephrine when measured by fluorimetric or photometric methods. (7.8)

USE IN SPECIFIC POPULATIONS

- Pregnancy (8.1)
 - Fetal/Neonatal Adverse Reactions – Sotalol has been shown to cross the placenta and is found in amniotic fluid.
 - Labor or Delivery – Risk of arrhythmias increases during the labor and delivery process. Patients treated with sotalol should be monitored continuously during labor and delivery.
- Lactation (8.2)
 - Sotalol is present in human milk in high levels.
 - Advise women not to breastfeed while on treatment with sotalol.
- Females and Males of Reproductive Potential (8.3)
 - Infertility – Based on the published literature, beta blockers (including sotalol) may cause erectile dysfunction.
- Pediatric Use (8.4)
 - Sotalol is indicated for:
 - The treatment of documented, life-threatening VT in pediatric patients
 - The maintenance of normal sinus rhythm [delay in time to recurrence of atrial fibrillation/atrial flutter (AFIB/AFL)] in pediatric patients with highly symptomatic AFIB/AFL who are currently in sinus rhythm.
 - Side effects from use of other sotalol-containing drug products in pediatric patients are those typical of a beta blocking agent.
 - Bradycardia may require emergency pacemaker implantation. Close inpatient monitoring is recommended until steady state drug levels are achieved.
- Renal Impairment (8.5)
 - Sotalol is eliminated predominantly via the kidney. Sotalol exposure increases with decrease in renal function. Sotalol dose should be reduced and interval between doses should be increased based on the patient's renal function.

These highlights do not include all the information needed to use sotalol hydrochloride injection safely and effectively. See full Prescribing Information for sotalol hydrochloride injection attached & www.sotaloliv.com/pi. For more information about Sotalol IV (sotalol hydrochloride injection) please visit our website at www.sotaloliv.com.



SOTALOL IV

sotalol hydrochloride injection
10mL vial (15mg/mL)

A **trusted** pediatric antiarrhythmic
Intravenous sotalol is **FDA approved** for pediatric use¹

How to Order

Sotalol IV (sotalol hydrochloride injection 10 mL vial [15 mg/mL]) is available through your wholesaler.

Product Description

Product	NDC Code	Description	Dimensions	Weight
10 mL Vial	69724-112-10	150 mg/10mL (15 mg/mL)	1.5"W x 1.5"D x 2.875"L	0.29 lbs

Item Numbers for Authorized Wholesalers

Use the below item numbers to order from your wholesaler for overnight delivery.

ASD Healthcare	Cardinal Health	Morris & Dickson	McKesson Plasma and Biologics
10251101	5222351	65143	3555158

Information on safe storage and shelf life of Sotalol IV¹

One carton contains one single-dose vial containing 150 mg/10 mL (15 mg/mL) sotalol hydrochloride injection, a clear and colorless solution. Store at 20° to 25°C (68° to 77°F); excursions permitted 15° to 30°C (59° to 86°F). Protect from freezing and light.

The expiration date of the product is always noted on the label on the vial.

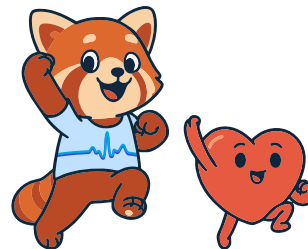
Get started with Sotalol IV.

Learn more about why intravenous sotalol could be right for your pediatric health practice.

sotaloliv.com/go/pediatrics

✉ customerservice@altathera.com

☎ 1-312-445-8900



References

1. Sotalol IV [package insert]. Chicago, IL: AltaThera Pharmaceuticals; 07/2025.
2. BetaPace AF (sotalol hydrochloride) [package insert]. Zug, CH: Covis Pharma; 06/2023.
3. Sotalol hydrochloride injection for intravenous use [package insert]. Lake Bluff, IL: Academic Pharmaceutical; 07/2009.
4. Sotalol IV [package insert]. Chicago, IL: AltaThera Pharmaceuticals; 03/2020.

WARNING: LIFE THREATENING PROARRHYTHMIA

Sotalol can cause life threatening ventricular tachycardia associated with QT interval prolongation. To minimize the risk of drug induced arrhythmia, initiate or uptitrate intravenous sotalol in a facility that can provide continuous electrocardiographic monitoring and cardiac resuscitation [see Dosage and Administration (2.3) and Warnings and Precautions (5.1)]

Do not initiate intravenous sotalol therapy if the baseline QTc is longer than 450 ms. If the QTc prolongs to 500 ms or greater, reduce the dose or discontinue.