# Sotylize®

## (sotalol hydrochloride) oral solution

5 mg/mL

**Product Fact Sheet**

### MANUFACTURED BY
Patheon Inc.
Whitby, ON L1N 5Z5 Canada

### DISTRIBUTED AND MARKETED BY
Azurity Pharmaceuticals, Inc, Woburn, MA 01801
Phone: 1-877-495-6858
Web: www.azurity.com
www.sotylize.com

### NDC CODE
NDC 24338-530-25, 5 mg/mL: 250 mL bottle
NDC 24338-530-48, 5 mg/mL: 480 mL bottle

### MINIMUM ORDER QUANTITY
1 250 mL or 1 480 mL bottle

### HOW SUPPLIED
5 mg/mL: 250 mL bottle
5 mg/mL: 480 mL bottle

### DATED ITEMS
The expiration date is printed on each bottle

### PRESCRIPTION LEGEND
Prescription only

### STORAGE REQUIREMENTS
Store at 20°C to 25°C (68°F to 77°F)
Excursions permitted between 15°C and 30°C (59°F to 86°F)

### HOW TO ORDER
Ordering available through wholesalers


### PRODUCT INFORMATION
**For medical information:**
Azurity Pharmaceuticals: 1-800-461-7449
or medical.information@azurity.com

To report an adverse event:
Azurity Pharmaceuticals: 1-800-461-7449
or aereports@azurity.com

FDA: 1-800-FDA-1088 (1-800-332-1088)
or www.fda.gov/medwatch

### DOSAGE AND STRENGTH
5 mg/mL oral solution

## IMPORTANT SAFETY INFORMATION

### WARNING: LIFE-THREATENING PROARRHYTHMIA
*See full Prescribing Information for complete boxed warning.*

- **Sotalol can cause life-threatening ventricular tachycardia associated with QT interval prolongation.**
- **If the QT interval prolongs to 500 msec or greater, reduce the dose, lengthen the dosing interval, or discontinue the drug.**
- **Initiate or reinitiate in facility that can provide cardiac resuscitation and continuous electrocardio graphic monitoring.**
- **Adjust the dosing interval based on creatinine clearance.**

**Please see additional Important Safety Information inside, as well as the enclosed full Prescribing Information.**
**Please see additional product information on back cover.**

# Sotylize®

## (sotalol hydrochloride) oral solution

5 mg/mL

**Product Fact Sheet**

Grape flavored

24-month shelf life
No refrigeration needed

Available in 250 mL and 480 mL bottles

Visit **Sotylize.com** to learn more and access the patient copay card.

**To place an order for Sotylize, please contact your wholesaler.**

| Product | NDC | Size | Amerisource-Bergen | Cardinal Health | H. D. Smith | McKesson | Morris & Dickson |
|---|---|---|---|---|---|---|---|
| Sotylize (sotalol hydrochloride) oral solution | 24338-530-25 | 250 mL bottle | 10148285 | 5060215 | 5400429 | 3426533 | 132100 |
| | 24338-530-48 | 480 mL bottle | 10148287 | 5050231 | 5400437 | 3426541 | 132290 |

## IMPORTANT SAFETY INFORMATION

### SOTYLIZE® (sotalol hydrochloride) oral solution

### INDICATIONS AND USAGE

SOTYLIZE® is an antiarrhythmic indicated for:

- The treatment of life-threatening ventricular arrhythmias
- The maintenance of normal sinus rhythm in patients with highly symptomatic atrial fibrillation/flutter (AFIB/AFL)

### WARNING: LIFE-THREATENING PROARRHYTHMIA

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azurity pharmaceuticals

Sotylize® (sotalol hydrochloride) oral solution 5 mg/mL

Azurity Pharmaceuticals, Inc. | 8 Cabot Road, Suite 2000, Woburn, MA 01801

# Sotylize®

(sotalol hydrochloride) oral solution

5 mg/mL

## IMPORTANT SAFETY INFORMATION (Cont.)

### Limitations of Use:

- SOTYLIZE has not been shown to enhance survival in patients with life-threatening ventricular arrhythmias
- Avoid use in patients with minimally symptomatic or easily reversible AFIB/AFL

### WARNING: LIFE-THREATENING PROARRHYTHMIA

*See full Prescribing Information for complete boxed warning.*

- **Sotalol can cause life-threatening ventricular tachycardia associated with QT interval prolongation.**
- **If the QT interval prolongs to 500 msec or greater, reduce the dose, lengthen the dosing interval, or discontinue the drug.**
- **Initiate or reinitiate in facility that can provide cardiac resuscitation and continuous electrocardiographic monitoring.**
- **Adjust the dosing interval based on creatinine clearance.**

## CONTRAINDICATIONS

For the treatment of AFIB/AFL or ventricular arrhythmias, SOTYLIZE is contraindicated in patients with:

- Baseline QT interval >450 msec
- Sinus bradycardia, sick sinus syndrome, second and third degree AV block, unless a functioning pacemaker is present
- Congenital or acquired long QT syndromes
- Cardiogenic shock or decompensated heart failure
- Serum potassium <4 mEq/L
- Bronchial asthma or related bronchospastic conditions
- Hypersensitivity to sotalol

## WARNINGS AND PRECAUTIONS

**QT Prolongation and Proarrhythmia:** SOTYLIZE can cause serious and potentially fatal ventricular arrhythmias such as sustained VT/VF, primarily Torsade de Pointes (TdP) type ventricular tachycardia, a polymorphic ventricular tachycardia associated with QT interval prolongation. Factors such as reduced creatinine clearance, female sex, higher doses, reduced heart rate, and history of sustained VT/VF or heart failure increases the risk of TdP. The risk of TdP can be reduced by adjustment of the sotalol dose according to creatinine clearance and by monitoring the ECG for excessive increases in the QT interval

Correct hypokalemia or hypomagnesemia prior to initiating SOTYLIZE, as these conditions can exaggerate the degree of QT prolongation, and increase the potential for Torsade de Pointes. Special attention should be given to electrolyte and acid-base balance in patients experiencing severe or prolonged diarrhea or patients receiving concomitant diuretic drugs.

Proarrhythmic events must be anticipated not only on initiating therapy, but with every upward dose adjustment.

Avoid use with other drugs known to cause QT prolongation.

**Bradycardia/Heart Block/Sick Sinus Syndrome:** Sinus bradycardia (heart rate less than 50 bpm) occurred in 13% of patients receiving sotalol in clinical trials, and led to discontinuation in about 3% of patients. Bradycardia itself increases the risk of Torsade de Pointes. Sinus pause, sinus arrest and sinus node dysfunction occur in less than 1% of patients. The incidence of 2nd- or 3rd-degree AV block is approximately 1%.

SOTYLIZE is contraindicated in patients with sick sinus syndrome because it may cause sinus bradycardia, sinus pauses or sinus arrest.

**Hypotension:** Sotalol produces significant reductions in both systolic and diastolic blood pressures and may result in hypotension. Monitor hemodynamics in patients with marginal cardiac compensation.

**Heart Failure:** New onset or worsening heart failure may occur during initiation or uptitration of sotalol because of its beta-blocking effects. Monitor for signs and symptoms of heart failure and discontinue treatment if symptoms occur.

## IMPORTANT SAFETY INFORMATION (Cont.)

**Cardiac Ischemia after Abrupt Discontinuation:** Following abrupt cessation of therapy with beta-adrenergic blockers, exacerbations of angina pectoris and myocardial infarction may occur. When discontinuing chronically administered SOTYLIZE, particularly in patients with ischemic heart disease, gradually reduce the dosage over a period of 1 to 2 weeks, if possible, and monitor the patient. If angina markedly worsens or acute coronary ischemia develops, treat appropriately and consider use of an alternative beta-blocker. Warn patients not to interrupt therapy without their physician's advice. Because coronary artery disease is common, but may be unrecognized, the abrupt discontinuation of sotalol may unmask latent coronary insufficiency.

**Bronchospasm:** Patients with bronchospastic diseases (for example chronic bronchitis and emphysema) should not receive beta-blockers. If SOTYLIZE is to be administered, use the smallest effective dose, to minimize inhibition of bronchodilation produced by endogenous or exogenous catecholamine stimulation of beta-2-receptors.

**Diabetes:** Beta-blockers may prevent early warning signs of hypoglycemia, such as tachycardia, and increase the risk for severe or prolonged hypoglycemia at any time during treatment, especially in patients with diabetes mellitus or children and patients who are fasting (i.e., surgery, not eating regularly, or are vomiting). Monitor blood sugar, as appropriate.

**Thyroid Abnormalities:** Avoid abrupt withdrawal of beta-blockers in patients with thyroid disease because it may lead to an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Beta-blockers may mask certain clinical signs (for example, tachycardia) of hyperthyroidism.

**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.

**Major Surgery:** Chronically administered beta-blocking therapy should not be routinely withdrawn prior to major surgery; however, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

## ADVERSE REACTIONS

The most common adverse reactions (>2%) for SOTYLIZE are: fatigue (4%), bradycardia [less than 50 bpm] (3%), dyspnea (3%), proarrhythmia (3%), asthenia (2%), and dizziness (2%).

## DRUG INTERACTIONS

*Antiarrhythmics and Other QT Prolonging Drugs*: Discontinue Class I or Class III antiarrhythmic agents for at least three half-lives prior to dosing with sotalol. Class Ia antiarrhythmic drugs such as disopyramide, quinidine and procainamide and other Class III drugs (for example, amiodarone) are not recommended as concomitant therapy with sotalol because of their potential to prolong refractoriness.

*Negative Chronotropes:* Digitalis glycosides, diltiazem, verapamil, and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use with negative chronotropes can increase the risk of bradycardia or hypotension.

*Catecholamine-Depleting Agents:* Concomitant use of catecholamine-depleting drugs, such as reserpine and guanethidine, with a beta-blocker may produce an excessive reduction of resting sympathetic nervous tone. Monitor such patients for hypotension and/or marked bradycardia which may produce syncope.

*Insulin and Oral Antidiabetics:* Hyperglycemia may occur, and the dosage of insulin or antidiabetic drugs may require adjustment.

*Beta-2-Receptor Stimulants*: Beta-agonists such as albuterol, terbutaline and isoproterenol may have to be administered in increased dosages when used concomitantly with sotalol.

*Clonidine:* Concomitant use with sotalol increases the risk of bradycardia and AV block. Because beta-blockers may potentiate the rebound hypertension sometimes observed after clonidine discontinuation, withdraw sotalol several days before the gradual withdrawal of clonidine to reduce the risk of rebound hypertension.

*Antacids:* Avoid administration of oral sotalol within 2 hours of antacids containing aluminum oxide and magnesium hydroxide.

*Drug/Laboratory Test Interactions*: The presence of sotalol in the urine may result in falsely elevated levels of urinary metanephrine when measured by flourimetric or photometric methods.

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**The Important Safety Information does not include all the information needed to use SOTYLIZE safely and effectively. Please see accompanying full Prescribing Information for SOTYLIZE.**

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**To Report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.**