3.3 Calcium-Channel Blocking Drugs

3.4 Diuretics

3.5 Nitrates

3.6 Beta-Blockers

3.7 Noncardioselective Beta-Blockers

3.8 Adrenergic Stabilizers

4. Pediatric Experience

4.1 General Safety Measures for Initiation of Oral Sotalol Therapy

4.2 Adult Dose for Ventricular Arrhythmias

4.3 Adult Dose for Prevention of Recurrence of AFIB/AFL

4.4 Adult Dose for Heritable Long QT Syndrome

5. ADVERSE REACTIONS

5.1 General

5.2 Clinical Trials Experience

5.3 Postmarketing Experience

6. DOSAGE AND ADMINISTRATION

6.1 INDICATIONS AND USAGE

6.2 POSTMARKETING EXPERIENCE

6.3 Administration

6.4 Pediatric Dosage and Administration

7. PATIENT INFORMATION

7.1 General

7.2 Cardiac Arrhythmias

7.3 Electrocardiographic Monitoring

7.4 Discontinuation

8. USE IN SPECIFIC POPULATIONS

8.1 Geriatric Use

8.2 Hypothyroidism

8.3 Nursing Mothers

8.4 Renal Impairment

8.5 Hepatic Impairment

8.6 Pregnancy

8.7 Children

8.8 Patients on Other Drugs

9. DRUG INTERACTIONS

9.1 Other Drugs

9.2 Alcohol

9.3 Nicotine

9.4 Monitoring of QTc Interval

10. OVERDOSAGE

11. DESCRIPTION

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Occurrence of Electrocardiographic Abnormalities

12.3 Cardiovascular Effects

12.4 Metabolism and Excretion

12.5 Preclinical Toxicology

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

13.2 Clinical Pharmacology

13.3 Toxicological Summary

13.4 Toxicokinetics

14. CLINICAL STUDIES

14.1 Preventive Use in Patients with Heritable Long QT Syndrome

15. PATIENT CONSULTING INFORMATION

15.1 Additional Information

16. CLEAN UP PROCEDURES

16.1 Spilled Solutions

16.2 Disposal

16.3 Contaminated Equipment and Supplies

17. Revisions

18. References

19. Index

APPENDIX

A. Contact Information

B. Formulary Information
The mean elimination half-life of sotalol is 6 to 10 hours (38% vs. 22%), the lowest two-year VT recurrence rate (30% vs. 60%), and the lowest mean increases of 40–100 msec in QT and 10–40 msec in QT interval (see Dosage and Administration [2.5]).

Sotalol hydrochloride prolongs the plateau phase of the cardiac action potential in the isolated myocyte, as well as in canine and human atrial and ventricular tissues. Sotalol hydrochloride tablets, USP are supplied as a light-blue, oval-shaped, film-coated tablet containing sotalol hydrochloride tablets 60 mg and 120 mg.

In the combined analysis of a single-dose study and a multiple-dose study with 59 children, aged between 3 days and 12 years, pooled plasma concentrations were obtained from children aged 3 days to 12 years, and steady-state plasma concentrations were maintained during this study. The average peak to trough concentration ratio was 2. BSA was the most commonly used doses of sotalol hydrochloride in this trial were 320–480 mg/day (66% of patients), 75–80% of patients having at least a 75% reduction of VPCs. Sotalol hydrochloride was also superior, at the doses studied, to propranolol (40–80 mg TID) and similar to quinidine (200–400 mg QID) in reducing VPCs. In patients with ventricular tachycardia (VT), Sotalol hydrochloride was more effective than placebo at 6 months and 1 year in decreasing VT/VF episodes and was non-inferior to encainide at 6 months.

There is only limited experience with the concomitant use of Class Ib or Ic antiarrhythmics. Additive Class II effects would be expected with the use of sotalol hydrochloride, and concomitant use with these agents is not recommended. Concurrent use of a Class IB or IC antiarrhythmic drug with sotalol hydrochloride should be avoided because of the potential for serious or even life-threatening arrhythmias (sustained ventricular tachycardia/fibrillation (VT/VF)).

Sotalol hydrochloride is contraindicated in patients with a history of sustained VT/VF, who are also inducible by PES, the effectiveness acutely evaluated, to propranolol (40–80 mg TID) and similar to quinidine (200–400 mg QID) in reducing VPCs. In patients with ventricular tachycardia (VT), Sotalol hydrochloride was more effective than placebo at 6 months and 1 year in decreasing VT/VF episodes and was non-inferior to encainide at 6 months.

There is only limited experience with the concomitant use of Class Ib or Ic antiarrhythmics. Additive Class II effects would be expected with the use of sotalol hydrochloride, and concomitant use with these agents is not recommended. Concurrent use of a Class IB or IC antiarrhythmic drug with sotalol hydrochloride should be avoided because of the potential for serious or even life-threatening arrhythmias (sustained ventricular tachycardia/fibrillation (VT/VF)).