

# Drug Information Sheet("Kusuri-no-Shiori")

Internal

Published: 12/2021

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

**Brand name:**Sotalol Hydrochloride Tablets 40mg "TE"

**Active ingredient:**Sotalol hydrochloride

**Dosage form:**faint blue tablet with split line, diameter: 7.2 mm, thickness: 3.1 mm

**Print on wrapping:**(face) ソタロール 「TE」, 40mg, 不整脈治療剤  
(back) ソタロール 「TE」, 40mg



**Effects of this medicine**

This medicine suppresses the sympathetic nervous system overactivity, a cause of arrhythmia, by blocking  $\beta$  receptor and potassium channel, and consequently normalizes the pulse.

It is usually used to treat recurrent arrhythmia of ventricular tachycardia and ventricular fibrillation.

**Before using this medicine, be sure to tell your doctor and pharmacist**

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.  
If you have cardiogenic shock, congestive heart failure, renal disorder, sinus bradycardia, conduction disturbance, bronchial asthma, bronchospasm or long QT syndrome.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

**Dosing schedule (How to take this medicine)**

- Your dosing schedule prescribed by your doctor is(( to be written by a healthcare professional))
- In general, for adults, start with taking 1 tablet (40 mg of the active ingredient) at a time, twice a day. If the effect is insufficient, the dosage may be gradually increased up to 4 tablets (160 mg) at a time, twice a day. Strictly follow the instructions.
- If you miss a dose, take a dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

**Precautions while taking this medicine**

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include bradycardia, headache, dizziness on standing up, nausea, general malaise and easy fatigability. If any of these symptoms occur, consult with your doctor or pharmacist.

**The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.**

- palpitation, shortness of breath, dizziness [ventricular fibrillation, ventricular tachycardia, Torsades de pointes, sinus pause, complete atrioventricular block]
- shortness of breath, general edema, cough [heart failure, cardiac dilatation]

**The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.**

**Storage conditions and other information**

- Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.