

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

Internal

Revised: 06/2018

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:Amiodarone Hydrochloride Tablets 50mg [TE]**

**Active ingredient:**Amiodarone hydrochloride

**Dosage form:**white tablet (diameter: 6.8 mm, thickness: 3.0 mm)

**Print on wrapping:**(face) アミオダロン「TE」, 不整脈治療剤, 50mg  
(back) アミオダロン 50mg「TE」, 速崩錠, 不整脈治療剤,  
TED1, 吸湿注意



## **Effects of this medicine**

This medicine works to relieve abnormal excitation of the heart by blocking the potassium channel of cardiac muscle, etc., and consequently normalize the pulse.

It is usually used for the treatment of recurrent arrhythmia.

## **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 sick sinus syndrome or atrioventricular block.
- 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))
- Introduction phase: In general, for adults, take 8 tablets (400 mg of the active ingredient) per day, in 1 to 2 divided doses for 1 to 2 weeks.  
Maintenance phase: In general, for adults, take 4 tablets (200 mg) per day in 1 to 2 divided doses.  
The dosage may be adjusted according to the patient's age and symptoms. Strictly follow the instructions.
- This medicine is a tablet preparation that rapidly disintegrates by water. Make sure you take it with water.
- If you miss a dose, take the dose when you realize you have missed a dose. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule from the next dose onwards. 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**

- Do not take health food products that contain hypericum perforatum (St. John's wort) as those products may increase metabolism of this drug and diminish the effect of this medicine. If you are already taking any of those food products, consult with your doctor or pharmacist.

## **Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include pulmonary function impairment, hyperthyroidism or hypothyroidism, visual disturbance, optic neuritis, rash, and photosensitivity. 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.**

- fever, dry cough, dyspnoea [interstitial pneumonia, pulmonary fibrosis, alveolitis]
- dizziness, chest pain, palpitation [exacerbation of arrhythmia, cardiac failure, bradycardia, cardiac arrest, complete atrioventricular block, decreased blood pressure]
- general malaise, loss of appetite, yellowing of the skin and the whites of the eyes [fulminant hepatitis, cirrhosis, liver disorder]
- convulsion, consciousness disturbed [syndrome inappropriate antidiuretic hormone]
- sputum bloody, haematemesis, dyspnoea [pulmonary alveolar haemorrhage]
- fever, chills, sore throat [agranulocytosis, leucopenia]

**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 infants and young children. Store away from light, heat and humidity.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution when you discard the medicine.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.