

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

External

Revised: 01/2019

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: Biso no tape 4mg

Active ingredient: Bisoprolol

Dosage form: white translucent tape, 42.5 mm*42.5 mm

Print on wrapping: ビソノテープ 4mg, 642 (on the aluminum bag)



Effects of this medicine

This medicine shows antihypertensive effect and antiarrhythmic effect by acting on the receptor of a neurotransmitter as well as reducing the excess work of the heart.

It is usually used for the treatment of essential hypertension (mild to moderate) or tachycardiac atrial 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 bradycardia, atrioventricular block, sinoatrial block, sick sinus syndrome, diabetic ketoacidosis, metabolic acidosis, cardiogenic shock, right heart failure due to pulmonary hypertension, decompensated heart failure, peripheral circulatory disturbance or untreated pheochromocytoma.
- If you are pregnant, possibly 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))
- For treatment of essential hypertension (mild to moderate): In general, for adults, apply 8 mg of the active ingredient at a time to the chest, upper arm or back, once daily. The tape should be changed every 24 hours. Treatment may be started with 4 mg once daily, depending on the age and symptoms. Maximum daily dosage is 8 mg.
For treatment of tachycardiac atrial fibrillation: In general, for adults, start with 4mg of the active ingredient at a time. The tape should apply to the chest, upper arm or back and be changed every 24 hours. If the dose seems to be insufficient, apply 8mg a day. The dosage may be adjusted depending on the age and symptoms, and maximum daily dose is 8mg.
Each sheet contains 4 mg of the active ingredient. Strictly follow the instructions.
- Dry the skin on the application site with a clean towel, etc. before applying the tape.
- Do not apply the tape to areas of wound or eczema, or those where you sweat easily.
- Press the tape applied on the skin with your palm to fix tightly.
- If the tape partially falls off, fix it with an adhesive bandage, etc. to keep the tape from coming off the skin.
- Confirm that the tape applied on the previous day has been peeled off, before applying the new tape.
- If you continue applying to the same place, it may cause itch, redness or dermatitis. Apply the new tape to the different place of previous application.
- If you miss changing the tape, replace the new tape as soon as possible and continue your regular application schedule from the next dose. However, if it is almost time for the next dose, skip the missed dose and follow your regular application schedule. You should never use two doses at one time.
- If you accidentally use more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop using this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause dizziness or light-headedness especially just after you begin to receive treatment. Be aware of operating in potentially hazardous activities such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include inflammation, redness and itch at the application site, bradycardia, and heart failure. 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.

- breathing difficulty, edema, weight increase [heart failure]
- dizziness, conscious disorder, bradycardia [complete atrioventricular block, severe bradycardia, sick sinus syndrome]

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 heat, moisture and light.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.