

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

Internal

Revised: 04/2023

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: Itorol tablets 20mg

Active ingredient: Isosorbide mononitrate

Dosage form: white tablet (diameter: 7.0 mm, thickness: 2.4 mm)

Imprint or print on wrapping: (face) アイトロール, 20 mg, 狭心症治療薬
(back) アイトロール, 20 mg, 狭心症治療薬, 122



Effects of this medicine

This medicine has vasodilatory effects on both peripheral and coronary arteries to increase blood flow. These effects improve the transport of both oxygen and nutrition into cardiac cells and reduce systemic vascular resistance, arterial pressure and workload in the heart.

It is usually used for the treatment of angina pectoris. It is not used for the acute relief of angina pectoris.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reaction (itch, rash etc.) to any medicines or foods.
If you have hypotension, cardiogenic shock, angle-closure glaucoma, head trauma, cerebral hemorrhage, or anemia.
- 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, take 1 tablet (20 mg of the active ingredient) at a time, twice a day, and this may be adjusted according to the age or symptoms. If the dose seems to be insufficient, take 2 tablets (40 mg) at a time, twice a day. If you are effort angina or effort and rest angina and determined serious condition on number of angina attack and exercise tolerance, take 2 tablets (40 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 follow 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

- Pay attention that drinking may enhance your sensitivity to the vasodilatory effect and cause hypotension.
- This medicine may impair your attentiveness, concentration and/or reflexes movement performance due to adverse reactions such as headache. If you feel these symptoms, avoid operating a motor vehicle or machinery.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include headache, dizziness/light headedness, palpitation, insomnia, general malaise, rash, itch, stomach heavy feeling and abdominal bloating. 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.

- general malaise, loss of appetite, yellowness in the skin and/or the white of eyes [liver dysfunction, jaundice]

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 reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of them, consult with your dispensing pharmacy or medical institution. Do not give this medicine to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.