

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

Internal

Revised: 04/2009

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 (  $\phi$  : 7.0 mm, thickness: 2.4 mm)

**Print on wrapping:** (face) 122, アイトロール 20 mg

(back) アイトロール, 20 mg



## 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.

This medicine is usually used for the prevention and treatment of angina pectoris. It is not used for the acute relief of angina pectoris.

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

- If you have previously experienced any allergic reaction (itch, rash etc.) to any medicine.  
If you have hypotension, 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) twice a day, and this may be adjusted depending on symptoms and age. If the dose seems to be insufficient, take 2 tablets (40 mg) twice a day. Strictly follow the instructions.
- If you miss a dose, immediately take a single normal dose. If your next regularly scheduled dose is more than 6 hours away, take your next dose according to your regular schedule. If your next regularly scheduled dose is less than 6 hours away, take your next dose 6 hours later and then return to 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

- Alcohol may enhance your sensitivity to the vasodilatory effect and cause hypotension.
- Headache, as a side effect, may impair your attentiveness, concentration and/or reflexes. 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, dull headache, dizziness, palpitation, rash and itch. 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 this medicine out of the reach of infants and children. Store away from heat, moisture and direct sunlight.
- Discard the remainder. Do not store them.

## For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.