

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

Internal

Revised: 08/2018

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:**IRBESARTAN TABLET 50mg 「OHARA」

**Active ingredient:**Irbesartan

**Dosage form:**white to yellowish white tablet, major axis: 8.6 mm, minor axis: 4.5 mm, thickness: 3.1 mm

**Print on wrapping:**イルベサルタン 50mg「オーハラ」, 血圧降下薬, 1日1回服用, Irbesartan50mg「OHARA」



**Effects of this medicine**

This medicine decreases blood pressure by antagonizing the type 1 angiotensin II receptor competitively. It is usually used to treat hypertension.

**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 are a patient with diabetes mellitus.
- 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))
- In general, for adults, take 1 to 2 tablets ( 50 to 100 mg of the active ingredient ) at a time, once a day. The dosage may be adjusted according to your age or symptoms. The maximum daily dose is 4 tablets (200 mg). Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, 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**

- The medicine may cause dizziness or lightheadedness due to decreased blood pressure. Pay attention when you work at heights, drive a car or operate dangerous machinery.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include dizziness, cough, headache, rash, hives 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.**

- breathing difficulty, swelling of face/tongue/throat [angioedema]
- numbness of limbs/lips, muscle weakness, paralysis of limbs [hyperkalemia]
- vomiting, faint, loss of consciousness [shock, syncope, loss of consciousness]
- edema, malaise, decreased urine output or anuria [renal failure]
- malaise, loss of appetite, yellowing of the skin and the white of eyes [hepatic 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 the reach of children. Store it at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Discard the remainder. Do not store them.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.

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