

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

Internal

Revised: 06/2016

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: GLIMEPIRIDE TABLETS 0.5mg 「OHARA」

Active ingredient: Glimepiride

Dosage form: white tablet, diameter: 4.5 mm, thickness: 1.8 mm

Print on wrapping: グリメピリド 0.5mg「オーハラ」, 0.5mg, 糖尿病用薬, OH-12,
Glimepiride 0.5mg「OHARA」



Effects of this medicine

This medicine promotes insulin secretion to lower blood glucose by mainly acting on beta cells of pancreas. It is usually used to treat type 2 diabetes mellitus.

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 ketosis, diabetic coma or precoma, insulin-dependent diabetes mellitus, liver disorder, kidney disorder, infection, an injury, gastrointestinal disorder such as diarrhea and vomiting, or inadequate food intake due to cold, etc.
- If you are in a pre- or post-operative state.
- 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, start taking 0.5 to 1 mg of the active ingredient, once or twice a day, before/after breakfast (once), or before/after breakfast and supper (twice). The maintenance dose is generally 1 to 4 mg a day and the dosage may be adjusted when needed. However, the maximum daily dose should not exceed 6 mg. This medicine contains 0.5 mg of the active ingredient in a tablet. Strictly follow the instructions.
- If you miss a 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

- Pay extra attention when performing dangerous operations such as working at heights or driving a car. If hypoglycemic symptom occurs during such operations, it may cause an accident.
- Carry a card stating that you are a patient with diabetes mellitus.
- Carry an adequate amount of sugar or glucose in preparation for hypoglycemia. If you are taking the medicine concomitantly with an alpha-glucosidase inhibitor (acarbose, voglibose, etc.), ingest glucose in case of any hypoglycemic symptoms.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include hypoglycemia, hypoglycemic symptoms, nausea, diarrhea and dizziness. 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.

- lassitude, feeling of hunger, sweating [hypoglycemia]
- fever, sore throat, general malaise, bleeding tendency (gum bleeding, nose bleeding, subcutaneous bleeding) [pancytopenia, agranulocytosis, hemolytic anemia, thrombocytopenia]
- general malaise, loss of appetite, yellowing of the skin and the white of the 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 the reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Ask the pharmacist and the medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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