

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

Internal

Revised: 03/2014

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:Amaryl tablets 0.5 mg

Active ingredient:Glimepiride

Dosage form:white tablet, diameter: 4.5 mm, thickness: 2.0 mm

Imprint or print on wrapping:アマリール 0.5, Amaryl 0.5, NM0.5, 糖尿病用薬



Effects of this medicine

This medicine mainly acts on pancreas to promote secretion of insulin.

It is usually used in the treatment of type II diabetes mellitus.

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 reactions (itch, rash, etc.) to any medicines or foods.
- If you have ketosis, diabetic coma or precoma, insulin-dependent diabetes mellitus, hepatic or renal disorder, infection, or gastrointestinal disorder such as diarrhea and vomiting.
- If you are in the pre/postoperative period.
- If you cannot take sufficient meal due to a cold, etc.
- 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 by taking 0.5 to 1 mg of the active ingredient, once to twice a day, in the morning or in the morning and evening, before or after meal. The maintenance dose is 1 to 4 mg a day in general and the dosage may be adjusted as necessary. However, the maximum daily dose is restricted to 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 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

- Be especially careful when you are engaged in dangerous activities such as working at heights and driving a car. Development of hypoglycemia during such activities may lead to an accident.
- Carry a card stating that you are a patient with diabetes mellitus.
- Carry sugar or glucose in preparation for hypoglycemia. If you are taking this medicine concomitantly with an alpha-glucosidase inhibitor (acarbose, voglibose, etc.), take glucose in case any hypoglycemic symptoms occur.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include hypoglycemia, hypoglycemic symptoms, queasiness, diarrhea, gastric discomfort 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.

- intense abnormal hunger, cold sweat, feelings of weakness, disturbance of consciousness [hypoglycemic symptoms]
- anemic symptoms (fatigability, general malaise, palpitation), fever, reddish brown urine [hemolytic anemia]
- throat pain, headache, high fever with chills and shivering [agranulocytosis]
- anemic symptoms (general malaise, palpitation), bleeding tendency (nasal bleeding), fever [pancytopenia]
- general malaise, loss of appetite, yellow discoloration of the skin/white of the 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 away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical facility when you discard the medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.