

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

Internal

Revised: 08/2015

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: Metformin Hydrochloride Tablets 500mg MT"TE"

Active ingredient: Metformin hydrochloride

Dosage form: faint yellow tablet (major axis: 13.7mm, minor axis: 8.7mm, thickness: 6.1mm)

Print on wrapping: (face) メトホルミン MT「TE」, 500mg, 糖尿病用薬, TEF2, (back) メトホルミン MT「TE」, 500mg, 糖尿病用薬, TEF2



Effects of this medicine

This medicine suppresses sugar production in the liver and prompts sugar utilization in the muscles in order to reduce sugar in the blood.

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 reaction (itch, rash etc.) to any medicine.
If you have previously had lactic acidosis.
- If you are a patient with renal/liver dysfunction, dehydration, gastrointestinal disorder (diarrhea, nausea etc.), type 1 diabetes mellitus, infection, or pituitary gland/adrenal disorder.
- If you are a patient with cardiovascular dysfunction (shock, heart failure, myocardial infarction etc.), pulmonary dysfunction (pulmonary embolism etc.), or any other condition likely to cause hypoxemia.
- If you are in a state of ketosis, in a diabetic coma or precoma, or in perioperative period.
- If you are receiving dialysis.
- If you are injured, malnourished, starvation, or debilitated.
- If you drink excessive alcohol.
- 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 >>
- **For adults:** In general, start with 1 tablet (500mg of the active ingredient) in 2 to 3 divided doses a day, either just before or after meal. The maintenance dose should be decided by judging the effectiveness of the medicine. Standard maintenance dose is 1.5 to 3 tablets (750 to 1500mg) in 2 to 3 divided dose a day. The dosage may be adjusted according to symptoms. The maximum dose is 4.5 tablets (2250mg) a day.
- **For children (10 years or older):** In general, start with 1 tablet (500mg) in 2 to 3 divided doses a day, either just before or after meal. The maintenance dose should be decided by judging the effectiveness of the medicine. Standard maintenance dose is 1 to 3 tablets (500 to 1500mg) in 2 to 3 divided dose a day. The dosage may be adjusted according to symptoms. The maximum dose is 4 tablets (2000mg) a day. 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

- Strictly follow the instruction on dietary/exercise therapy.
- Please note that dehydration, sick day (fever, diarrhea, vomiting, etc.) or excessive alcohol intake is likely to increase risk of lactic acidosis.
- You may have hypoglycemic symptoms (see side effects section below). Therefore do not work at heights, drive a car while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, vomiting, 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.

- gastrointestinal symptoms such as nausea and vomiting, over breathing (deep and hyper breathing), decreased consciousness [lactic acidosis]

- lassitude, hunger, sweating [hypoglycemia]
- general malaise, loss of appetite, yellowness in the skin and the white of the eye [liver dysfunction, jaundice]
- muscle pain, feeling of weariness, red-brown urine [rhabdomyolysis]

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 institution when you discard the medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.