

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

Internal

Revised: 12/2022

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 with split line, major axis: 13.7mm, minor axis: 8.7mm, thickness: 6.1mm

Imprint or 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 for the treatment of type 2 diabetes mellitus or for ovulation induction in polycystic ovary syndrome and controlled ovarian stimulation in assisted reproductive technology for polycystic ovary syndrome with obesity, impaired glucose tolerance, or insulin resistance.

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 reaction (itch, rash etc.) to any medicines or foods.
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 type 2 diabetes mellitus: In general, for adults, start with 1 tablet (500 mg 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 1,500 mg) in 2 to 3 divided dose a day. In general, for children (10 years or older), start with 1 tablet (500 mg) 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 1,500 mg) in 2 to 3 divided dose a day. The dosage may be adjusted according to symptoms. The maximum dose is 4.5 tablets (2,250 mg) a day for adults, 4 tablets (2,000 mg) a day for children.
For ovulation induction in polycystic ovary syndrome and controlled ovarian stimulation in assisted reproductive technology for polycystic ovary syndrome: In general, in combination with other ovulation inducing agent or ovarian stimulant, start with 1 tablet (500 mg) at a time, once a day. If tolerated, the dosage may be increased up to 3 tablets (1,500 mg) in 2 to 3 divided doses a day. The dosage will be stopped before ovulation or ovum collection. In any case, 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.
- Follow your doctor's instructions and take regular blood and urine tests.
- Pay attention that dehydration, sick day (fever, diarrhea, vomiting, etc.) or excessive alcohol intake is likely to increase risk of lactic acidosis (gastrointestinal symptoms such as nausea and vomiting, malaise, muscular pain,

breathing difficulty).

- If you receive an iodinated contrast test, this medicine should be temporarily discontinued before the test because you may have lactic acidosis. Also, do not take this medicine for 48 hours after the iodinated contrast test.
- You may have hypoglycemic symptoms (hungry, cold sweat, pale face, easy tiredness, tremor of limbs, convulsions, decreased consciousness, etc.). Pay close attention when you work at heights, drive a car.
- If you experience hypoglycemic symptoms, take foods containing sugar or sugar in general.
- Please inform your family about any precautions regarding hypoglycemia.
- If you are breastfeeding, avoid breastfeeding while taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, nausea, loss of appetite, abdominal pain and vomiting. 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, malaise, muscular pain, breathing difficulty [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. If you do not know how to dispose of them, consult with your dispensing pharmacy or medical institution. Do not give this medicine to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.