

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

Internal

Revised: 06/2017

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:ACTOS Tablets 15

Active ingredient:Pioglitazone hydrochloride

Dosage form:white to yellowish white tablet, diameter: 7.0 mm, thickness: 2.4 mm

Imprint or print on wrapping:(Face) 390, (Back) アクトス 15



Effects of this medicine

This medicine improves hyperglycemia by enhancing the action of insulin.

It is usually used to treat type 2 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 a heart disease or a history of heart disease, ketosis, diabetic coma or precoma, type 1 diabetes mellitus, hepatic disorder, renal disorder or severe infection; are in a pre- or post-operative state; have an injury, pituitary abnormality, adrenal disorder, inadequate food intake or debility; are doing strenuous physical exercise or a heavy drinker; have a bladder cancer/a history of bladder cancer or diabetic retinopathy.
- 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 (15 to 30 mg of pioglitazone) at a time, once a day, before or after breakfast. The dosage may be adjusted according the gender, age and symptoms, but 3 tablets (45 mg) a day is the upper limit of dosage.
When given concomitantly with an insulin preparation, in general, for adults, take 1 tablet (15 mg of pioglitazone) at a time, once a day, before or after breakfast. The dosage may be adjusted according to the gender, age and symptoms, but 2 tablets (30 mg) a day is the upper limit of dosage.
In any case, strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible if prior to noon. As hypoglycemia may occur, do not take this medicine after severe exercise or on an empty stomach. 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 instructions on dietary/exercise therapy.
- This medicine may cause hypoglycemia. Pay close attention when working at heights or operating dangerous machinery such as driving a car. Make sure to tell your family and persons around you that you are taking this medicine.
- When hypoglycemia symptoms occur, take an adequate amount of sugar (e.g., sugar, glucose, soft drinks). If you are taking this medicine concomitantly with an α -glucosidase inhibitor (medicines which delay absorption of sugar such as voglibose and acarbose), ingest glucose in case of any hypoglycemic symptoms.
- Increase in the potential risk of developing bladder cancer in patients taking this medicine cannot be completely denied. Therefore, patients taking this medicine are followed by periodic urinary tests, etc. If bloody urine, frequent urination, painful urination, etc. appear, consult with your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include anemia, blood pressure rising, palpitation, pressure in chest, facial flush, rash, itching, nausea, vomiting, gastric distress, heartburn, abdominal pain, abdominal enlarged feeling, diarrhea, constipation, bulimia, loss of appetite, dizziness, light headedness, headache, sleepiness, malaise, lassitude, numbness, increased body weight, aggravation of diabetic retinopathy and shortness of breath. 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.

- edema, rapid increase in body weight, shortness of breath, palpitation [heart or cardiac failure]
- edema, rapid increase in body weight [edema]

- loss of appetite, yellowing of the skin and the white of eyes [liver disorder/jaundice]
- cold sweat, a sense of hunger, shivering of limbs [hypoglycemia]
- lassitude, muscle pain, brown urine [rhabdomyolysis]
- pain in the pit of the stomach, nausea, black stool [relapse of gastric ulcer]
- fever, cough, respiratory distress [interstitial pneumonia]

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 reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.