

ACTOS TABLET®

Pioglitazone hydrochloride (15mg, 30mg)

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What Actos is used for

- Actos is used as oral monotherapy in type 2 diabetes mellitus patients, particularly overweight patients whom are inadequately controlled by diet and exercise.
- Actos is used for oral combination treatment in type 2 diabetes mellitus patients with insufficient glycaemic control despite maximal tolerated dose of oral monotherapy with either metformin or sulphonylurea.

How Actos works

Actos is a thiazolidinedione antidiabetic agent that depends on the presence of insulin for its mechanism of action. It acts primarily by decreasing insulin resistance. It decreases insulin resistance in the body, resulting in increased insulin-dependent glucose disposal and decreased hepatic glucose output.

Before you use Actos

- When you must not use it

- Do not use Actos if you are:
- a) Hypersensitive to pioglitazone or to any of the excipients of the tablet

- b) Having cardiac failure or history of cardiac failure (NYHA stages I to IV)
- c) The patient of hepatic impairment
- d) Pregnancy and lactation
- e) A type 1 diabetes patient

- Before you start to use it

- You must undergo blood tests for liver function prior to the start of therapy, and periodically thereafter per clinical judgment of the health care professional.
- Talk to your doctor if you are pregnant.

- Taking other medicines

- Actos can be co-administered with:
 - a) Oral contraceptives
 - b) Fexofenadine HCl
 - c) Glipizide
 - d) Digoxin
 - e) Warfarin
 - f) Metformin
 - g) Midazolam
 - h) Ranitidine HCl
 - i) Nifedipine ER
 - j) Ketoconazole
 - k) Atorvastatin Calcium
 - l) Theophylline
 - m) Cytochrome P450

Tell your doctor if you are taking any of the following medicines:

- a) Medicine containing insulin
- b) Medicine containing oral hypoglycemic agents

This is because the combination therapy with either one of the above medicine may cause the risks of hypoglycemia.

How to use Actos

- How much to use

You may start with 15mg or 30mg once daily. The dose may be increased in increments up to 45mg once daily.

Use in the elderly, no dosage adjustment is necessary for elderly patients.

Use in children, Actos is not recommended in patients under 18 years old.

Use in impaired renal function, no dosage adjustment is necessary.

Use in pregnancy, there are no adequate and well-controlled studies in pregnant women. Discuss with your doctor before taking Actos.

- When to use it

Actos should be taken orally, once daily with or without meals.

- How long to use it

Continue using Actos for as long as your doctor recommends.

- If you forget to use it

Continue using Actos for as long as your doctor recommends.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- You must adhere to dietary instructions from your doctor and have blood glucose and glycosylated hemoglobin tested regularly. During periods of stress such as fever, trauma, infection, or surgery, medication requirements may change and

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patients should be reminded to seek medical advice promptly. - If you experience an unusually rapid increase in weight or edema or develop shortness of breath or other symptoms of heart failure while on Actos, you should immediately report these symptoms to your doctor. - You should seek immediate medical advice for unexplained nausea, vomiting, abdominal pain, fatigue, anorexia or dark urine. - Patients may be at an increased risk for pregnancy while taking Actos. - <u>Things you must not do</u> - Do not stop taking the medicine unless advised by your doctor. - Do not take any new medicines without consulting your doctor or pharmacist. - Do not give Actos to anyone else, even if they have the same symptoms or condition as you. - <u>Things to be careful of</u> Actos can cause fluid retention. Fluid retention may lead to or exacerbate heart failure. You should talk to your doctor if there is any deterioration in cardiac status. Side effects Like all medicines, Actos can cause side effects, although not everybody gets them. The side effects of Actos are listed as below: - Upper respiratory tract infection - Headache - Sinusitis - Myalgia - Tooth disorder - Diabetes mellitus aggravated - Pharyngitis	Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]. Storage and Disposal of Actos - <u>Storage</u> Keep out of the reach and sight of children. Store below 30°C. Do not use Actos after the expiry date which is printed on the carton. - <u>Disposal</u> Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. Product Description - <u>What it looks like</u> Actos is white to yellowish white tablet. - <u>Ingredients</u> - Active ingredient(s) Pioglitazone hydrochloride - Inactive ingredients Purified water, magnesium stearate, hydroxypropylcellulose, carmellose calcium, lactose hydrate - <u>MAL number:</u>	MAL11100026ACZ MAL20051431ACZ Manufacturer Bora Pharmaceutical Laboratories Inc. No. 1, Kedong 3rd Rd., Hsinchu Science Park, Zhunan Township, Miaoli County, Taiwan, R.O.C. Product Registration Holder DKSH MALAYSIA SDN. BHD. B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia. Date of revision 20 May 2025 Serial Number NPRA (R1/5) 20052025/080
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