

MEDICATION GUIDE

ACTOS[®] (ak-TŌS) (pioglitazone hydrochloride) tablets

Read this Medication Guide carefully before you start taking ACTOS and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about ACTOS, ask your doctor or pharmacist.

What is the most important information I should know about ACTOS?

ACTOS can cause serious side effects, including new or worse heart failure.

- ACTOS can cause your body to keep extra fluid (fluid retention), which leads to swelling (edema) and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure. Heart failure means your heart does not pump blood well enough
- Do not take ACTOS if you have severe heart failure
- If you have heart failure with symptoms (such as shortness of breath or swelling), even if these symptoms are not severe, ACTOS may not be right for you

Call your doctor right away if you have any of the following:

- swelling or fluid retention, especially in the ankles or legs
- shortness of breath or trouble breathing, especially when you lie down
- an unusually fast increase in weight
- unusual tiredness

ACTOS can have other serious side effects. See “What are the possible side effects of ACTOS?”

What is ACTOS?

ACTOS is a prescription medicine used with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes. ACTOS is a diabetes medicine called pioglitazone hydrochloride that may be taken alone or with other diabetes medicines.

It is not known if ACTOS is safe and effective in children.

Who should not take ACTOS?

See “What is the most important information I should know about ACTOS?”

Do not take ACTOS if you:

- have severe heart failure
- are allergic to any of the ingredients in ACTOS. See the end of this Medication Guide for a complete list of ingredients in ACTOS

Talk to your doctor before taking ACTOS if you have either of these conditions.

What should I tell my doctor before taking ACTOS?

Before you start taking ACTOS, tell your doctor if you:

- **have heart failure**
- **have type 1 (“juvenile”) diabetes or had diabetic ketoacidosis**

- **have a type of diabetic eye disease that causes swelling in the back of the eye (macular edema)**
- **have liver problems**
- **are pregnant or plan to become pregnant.** It is not known if ACTOS will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant about the best way to control your blood glucose levels while pregnant
- **are a premenopausal woman (before the “change of life”) who does not have periods regularly or at all.** ACTOS may increase your chance of becoming pregnant. Talk to your doctor about birth control choices while taking ACTOS. Tell your doctor right away if you become pregnant while taking ACTOS
- **are breast-feeding or plan to breast-feed.** It is not known if ACTOS passes into your milk and if it can harm your baby. You should not take ACTOS if you breastfeed your baby. Talk to your doctor about the best way to control your blood glucose levels while breastfeeding

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements.

ACTOS and some of your other medicines can affect each other. You may need to have your dose of ACTOS or certain other medicines changed.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist before you start a new medicine. They will tell you if it is okay to take ACTOS with other medicines.

How should I take ACTOS?

- Take ACTOS exactly as your doctor tells you to take it
- Your doctor may change your dose of ACTOS. Do not change your ACTOS dose unless your doctor tells you to
- ACTOS may be prescribed alone or with other diabetes medicines. This will depend on how well your blood sugar is controlled
- Take ACTOS 1 time each day, with or without food
- If you miss a dose of ACTOS, take your next dose as prescribed unless your doctor tells you differently. Do not take two doses at one time the next day
- If you take too much ACTOS, call your doctor or go to the nearest hospital emergency room right away
- If your body is under stress such as from a fever, infection, accident, or surgery the dose of your diabetes medicines may need to be changed. Call your doctor right away
- Stay on your diet and exercise programs and test your blood sugar regularly while taking ACTOS
- Your doctor should do certain blood tests before you start and while you take ACTOS
- Your doctor should also do hemoglobin A1C testing to check how well your blood sugar is controlled with ACTOS
- Your doctor should check your eyes regularly while you take ACTOS
- It may take 2 to 3 months to see the full effect of ACTOS on your blood sugar level.

What are the possible side effects of ACTOS?

ACTOS may cause serious side effects including:

- See “What is the most important information about ACTOS.”
- **liver problems.** Call your doctor right away if you have:
 - nausea or vomiting
 - stomach pain
 - unusual or unexplained tiredness
 - loss of appetite
 - dark urine
 - yellowing of your skin or the whites of your eyes
- **broken bones (fractures).** Usually in the hand, upper arm, or foot in women. Talk to your doctor for advice on how to keep your bones healthy.
- **bladder cancer.** There may be an increased chance of having bladder cancer when you take ACTOS. You should not take ACTOS if you are receiving treatment for bladder cancer. Tell your doctor right away if you have any of the following symptoms of bladder cancer:
 - blood or a red color in your urine
 - an increased need to urinate
 - pain while you urinate
- **low blood sugar (hypoglycemia).** This can happen if you skip meals, if you also use another medicine that lowers blood sugar, or if you have certain medical problems. Lightheadedness, dizziness, shakiness, or hunger may happen if your blood sugar is too low. Call your doctor if low blood sugar levels are a problem for you
- **diabetic eye disease with swelling in the back of the eye (macular edema).** Tell your doctor right away if you have any changes in your vision. Your doctor should check your eyes regularly
- **release of an egg from an ovary in a woman (ovulation) leading to pregnancy.** Ovulation may happen when premenopausal women who do not have regular monthly periods take ACTOS. This can increase your chance of getting pregnant

The most common side effects of ACTOS include:

- cold-like symptoms (upper respiratory tract infection)
- headache
- sinus infection
- muscle pain
- sore throat

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the side effects of ACTOS. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ACTOS?

- Store ACTOS at 59°F to 86°F (15°C to 30°C). Keep ACTOS in the original container and protect from light

- Keep the ACTOS bottle tightly closed and protect from getting wet (away from moisture and humidity)
- Keep ACTOS and all medicines out of the reach of children

General information about the safe and effective use of ACTOS

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ACTOS for a condition for which it was not prescribed. Do not give ACTOS to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about ACTOS. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ACTOS that is written for healthcare professionals. For more information, go to www.actos.com or call 1-877-825-3327.

What are the ingredients in ACTOS?

Active Ingredient: pioglitazone hydrochloride

Inactive Ingredients: lactose monohydrate, hydroxypropylcellulose, carboxymethylcellulose calcium, and magnesium stearate.

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