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Patient Information
ACTOS® (ak-TŌS)
(pioglitazone hydrochloride)
Tablets

Read the Patient Information that comes with ACTOS before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

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.
- If you have severe heart failure, you cannot start on ACTOS.
- 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
- feel unusually tired

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 may be taken alone or with other diabetes medicines.

It is important to eat the right foods, lose weight if needed, and exercise regularly in order to manage your type 2 diabetes. Diet, weight loss, and exercise are the main treatment for type 2 diabetes and they also help your diabetes medicines work better for you.

ACTOS has not been studied in children and is not recommended for children under the age of 18.

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Who should not take ACTOS?

Do not take ACTOS if you:

- **are allergic to any of the ingredients in ACTOS.** See the end of this leaflet for a complete list of ingredients in ACTOS.
- **Certain patients with heart failure should not start taking ACTOS.** “See What is the most important information I should know about ACTOS?”
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What should I tell my doctor before taking ACTOS?

Tell your doctor about all of your medical conditions, especially if you:

- **have heart failure.**
- **have type 1 (“juvenile”) diabetes or had diabetic ketoacidosis.** These conditions should be treated with insulin.
- **have liver problems.** Your doctor should do blood tests to check your liver before you start taking ACTOS and during treatment as needed.
- **have a type of diabetic eye disease called macular edema** (swelling of the back of the eye).
- **are pregnant or planning to become pregnant.** It is not known if ACTOS can harm your unborn baby. ACTOS is not recommended for pregnant women. Talk to your doctor 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 breastfeeding.** 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 nonprescription medicines, vitamins, and herbal supplements. ACTOS and some of your other medicines can interact with each other. You may need to have your dose of ACTOS or certain other medicines adjusted. Certain other medicines can affect your blood glucose control.

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 okay to take ACTOS with other medicines.

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How should I take ACTOS?

- Take ACTOS exactly as prescribed. Your doctor may need to change your dose of ACTOS to control your blood glucose. Do not change your dose unless told to do so by your doctor.
- Take ACTOS one time each day.
- Take ACTOS either 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 poison control center right away.
- If your body is under stress, for example: due to fever, trauma (such as a car 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 blood tests to check your liver before you start ACTOS and during treatment as needed.
- Your doctor should also do regular blood tests (for example, hemoglobin A1C) to check how well your blood sugar is controlled with ACTOS.
- Your doctor should check your eyes regularly. Some patients have had vision changes due to swelling in the back of the eye, called macular edema, while taking ACTOS.

What are the possible side effects of ACTOS?

ACTOS can cause serious side effects including:

- **New or worse heart failure.** See "What is the most important information I should know about ACTOS?"

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- **Low blood sugar (hypoglycemia).** Feeling lightheaded, dizzy, shaky or hungry may mean that your blood sugar is too low. This can happen if you skip meals, if you use another medicine that lowers blood sugar, or if you have certain medical problems. Call your doctor if low blood sugar levels are a problem for you.
- **Swelling (edema).** ACTOS can cause swelling due to fluid retention. See “What is the most important information I should know about ACTOS?”
- **Weight gain.** ACTOS can cause weight gain that may be due to fluid retention or extra body fat. Weight gain due to fluid retention can be a serious problem for people with certain heart problems. See “What is the most important information I should know about ACTOS?”
- **Ovulation** (release of an egg from an ovary in a woman) leading to pregnancy. Ovulation may happen when premenopausal women who do not have regular monthly periods take ACTOS. This can increase the chance of pregnancy. See “What should I tell my doctor before taking ACTOS?”
- **Low red blood cell count (anemia).**
- **Liver problems.** It is important for your liver to be working normally when you take ACTOS. Your doctor should do blood tests to check your liver before you start ACTOS and during treatment as needed. Call your doctor right away if you have unexplained symptoms such as:
 - nausea or vomiting
 - stomach pain
 - unusual or unexplained tiredness
 - loss of appetite
 - dark urine
 - yellowing of your skin or the whites of your eyes
- **Macular edema** (a type of swelling in the back of the eye that can affect your vision). **Tell your doctor right away if you have any changes in your vision.**

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- **Bone fractures**, usually in the hand, upper arm or foot, in females. Talk to your doctor for advice on how to keep your bones healthy.

Common side effects of ACTOS include:

- cold-like symptoms
- headache
- sinus infection
- muscle pain
- tooth disorder
- 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 the ACTOS container closed tightly.
- Keep ACTOS from getting wet (away from moisture and humidity).

Keep ACTOS and all medicines out of the reach of children.

General information about ACTOS

Medicines are sometimes prescribed for conditions that are not mentioned in the patient information leaflet. 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.

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This leaflet 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 health 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 NF, hydroxypropylcellulose NF, carboxymethylcellulose calcium NF, and magnesium stearate NF.

Issued Month Year

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