

Medication Guide

Pioglitazone Tablets, USP

(pye'' oh gli' ta zone)

Read this Medication Guide carefully before you start taking pioglitazone tablets 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 pioglitazone tablets, ask your doctor or pharmacist.

What is the most important information I should know about pioglitazone tablets?

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

- Pioglitazone tablets 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 pioglitazone tablets 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, pioglitazone tablets 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

Pioglitazone tablets can have other serious side effects. See **“What are the possible side effects of pioglitazone tablets?”**

What are pioglitazone tablets?

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

It is not known if pioglitazone tablets are safe and effective in children under the age of 18.

Pioglitazone tablets are not recommended for use in children.

Pioglitazone tablets are not for people with type 1 diabetes.

Pioglitazone tablets are not for people with diabetic ketoacidosis (increased ketones in your blood or urine).

Who should not take pioglitazone tablets?

See **“What is the most important information I should know about pioglitazone tablets?”**

Do not take pioglitazone tablets if you:

- have severe heart failure

- are allergic to any of the ingredients in pioglitazone tablets. See the end of this Medication Guide for a complete list of ingredients in pioglitazone tablets.

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

What should I tell my doctor before taking pioglitazone tablets?

Before you take pioglitazone tablets, 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
- have or have had cancer of the bladder
- are pregnant or plan to become pregnant. It is not known if pioglitazone tablets can 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. Pioglitazone tablets may increase your chance of becoming pregnant. Talk to your doctor about birth control choices while taking pioglitazone tablets. Tell your doctor right away if you become pregnant while taking pioglitazone tablets.
- are breastfeeding or plan to breastfeed. It is not known if pioglitazone hydrochloride passes into your milk and if it can harm 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 over the counter medicines, vitamins, and herbal supplements. Pioglitazone tablets and some of your other medicines can affect each other. You may need to have your dose of pioglitazone tablets 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 pioglitazone tablets with other medicines.

How should I take pioglitazone tablets?

- Take pioglitazone tablets exactly as your doctor tells you to take it.
- Your doctor may change your dose of pioglitazone tablets. Do not change your pioglitazone tablets dose unless your doctor tells you to.
- Pioglitazone tablets may be prescribed alone or with other diabetes medicines. This will depend on how well your blood sugar is controlled.
- Take pioglitazone tablets one time each day, with or without food.
- If you miss a dose of pioglitazone tablets, 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 many pioglitazone tablets, 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 pioglitazone tablets.
- Your doctor should do certain blood tests before you start and while you take pioglitazone tablets.
- Your doctor should also do hemoglobin A1C testing to check how well your blood sugar is controlled with pioglitazone tablets.
- Your doctor should check your eyes regularly while you take pioglitazone tablets.

What are the possible side effects of pioglitazone tablets?

Pioglitazone tablets may cause serious side effects including:

- See “What is the most important information I should know about pioglitazone tablets?”
- **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.
- **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
- **bladder cancer.** There may be an increased chance of having bladder cancer when you take pioglitazone tablets. You should not take pioglitazone tablets 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 red color in your urine
 - an increased need to urinate
 - pain while you urinate
- **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.
- **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 pioglitazone tablets. This can increase your chance of getting pregnant.

The most common side effects of pioglitazone tablets 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 pioglitazone tablets. 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 pioglitazone tablets?

- Store pioglitazone tablets at 20° to 25°C (68° to 77°F). Keep pioglitazone tablets in the original container and protect from light
- Keep the pioglitazone tablets bottle tightly closed and keep tablets dry
- Keep pioglitazone tablets and all medicines out of the reach of children

General information about the safe and effective use of pioglitazone tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use pioglitazone tablets for a condition for which it was not prescribed. Do not give pioglitazone tablets 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 pioglitazone tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about pioglitazone tablets that is written for healthcare professionals. For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

What are the ingredients in pioglitazone tablets?

Active Ingredient: pioglitazone hydrochloride

Inactive Ingredients: hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulfate and sodium starch glycolate (potato).

This Medication Guide has been approved by the U.S. Food and Drug Administration.



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