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MEDICATION GUIDE
Pioglitazone and Metformin Hydrochloride
(pye'' oh gli' ta zone and met for' min hye'' droe klor' ide)
Tablets, USP

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

What is the most important information I should know about pioglitazone and metformin hydrochloride tablets?
Pioglitazone and metformin hydrochloride tablets can cause serious side effects, including:

- **Heart failure.** Pioglitazone, one of the medicines in pioglitazone and metformin hydrochloride 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.
  Before you start taking pioglitazone and metformin hydrochloride tablets:
  Tell your healthcare provider if you have ever had heart failure or have problems with your kidneys
  Call your healthcare provider right away if you have any of the following:
  - increasing shortness of breath or trouble breathing, especially when you lie down
  - an unusually fast increase in weight
  - swelling or fluid retention, especially in the ankles or legs
  - unusual tiredness

  These may be symptoms of heart failure.
- **Lactic acidosis.** Metformin, one of the medicines in pioglitazone and metformin hydrochloride tablets, can cause a rare but serious condition called lactic acidosis (a buildup of an acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.
  Stop taking pioglitazone and metformin hydrochloride tablets and call your healthcare provider right away if you have any of the following symptoms, which could be signs of lactic acidosis:
  - feel very weak or tired
  - have unusual (not normal) muscle pain
  - have trouble breathing
  - have unusual sleepiness or sleep longer than usual
  - have unexplained stomach or intestinal problems with nausea, vomiting, or diarrhea
  - feel cold, especially in your arms and legs
  - feel dizzy or lightheaded
  - have a slow or irregular heartbeat

  Most people who have had lactic acidosis with metformin have other things that, combined with the metformin, led to the lactic acidosis. Tell your healthcare provider if you have any of the following, because you have a higher chance for getting lactic acidosis with pioglitazone and metformin hydrochloride tablets if you:
  - have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye.
  - have liver problems
  - drink alcohol very often, or drink a lot of alcohol in short-term ("binge" drinking)
  - get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids
  - have surgery
  - have a heart attack, severe infection, or stroke
  - are 65 years of age or older

  The best way to keep from having a problem with lactic acidosis from metformin is to tell your healthcare provider if you have any of the problems in the list above. Your healthcare provider may decide to stop your pioglitazone and metformin hydrochloride tablets for a while if you have any of these things.

Pioglitazone and metformin hydrochloride tablets can have other serious side effects. See "What are the possible side effects of pioglitazone and metformin hydrochloride tablets?".

What are pioglitazone and metformin hydrochloride tablets?
Pioglitazone and metformin hydrochloride tablets are a prescription medicine that contains 2 diabetes medicines, pioglitazone (ACTOS) and metformin hydrochloride (GLUCOPHAGE). Pioglitazone and metformin hydrochloride tablets are used along with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes.
Pioglitazone and metformin hydrochloride tablets are not for people with type 1 diabetes.
Pioglitazone and metformin hydrochloride tablets are not for people with diabetic ketoacidosis (increased ketones in your blood or urine).
It is not known if pioglitazone and metformin hydrochloride tablets are safe and effective in children under the age of 18. Pioglitazone and metformin hydrochloride tablets are not recommended for use in children.

Who should not take pioglitazone and metformin hydrochloride tablets?
See "What is the most important information I should know about pioglitazone and metformin hydrochloride tablets?".
Do not take pioglitazone and metformin hydrochloride tablets if you:

- have severe heart failure
- have severe kidney problems
- have a condition called acute or chronic metabolic acidosis, including diabetic ketoacidosis.
- are allergic to pioglitazone, metformin, or any of the ingredients in pioglitazone and metformin hydrochloride tablets or have had a serious allergic (hypersensitivity) reaction to pioglitazone or metformin. See the end of this Medication Guide for a complete list of ingredients in pioglitazone and metformin hydrochloride tablets. Symptoms of a serious allergic reaction to pioglitazone and metformin hydrochloride tablets may include:
  - swelling of your face, lips, throat and other areas on your skin
  - raised, red areas on your skin (hives)
  - difficulty with swallowing or breathing
  - skin rash, itching, flaking or peeling

If you have these symptoms, stop taking pioglitazone and metformin hydrochloride tablets and contact your healthcare provider or go to the nearest hospital emergency room right away.
Tell your healthcare provider before taking pioglitazone and metformin hydrochloride tablets if you have any of these conditions.

What should I tell my healthcare provider before taking pioglitazone and metformin hydrochloride tablets?
Before you take pioglitazone and metformin hydrochloride tablets, tell your healthcare provider if you:

- have heart failure
- have kidney or liver problems
- are going to have dye injected into a vein for an x-ray, CAT scan, heart study, or other type of scanning
- will be undergoing a surgical procedure
- drink a lot of alcohol (all the time or short binge drinking)
- 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 low levels of vitamin B_{12} in your blood
- have or have had cancer of the bladder
- **are pregnant or plan to become pregnant.** It is not known if pioglitazone and metformin hydrochloride tablets can harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant about the best way to control your blood glucose levels while pregnant
- **are a woman who has not gone through menopause (premenopausal), who does not have periods regularly or at all.** Pioglitazone and metformin hydrochloride tablets may increase your chance of becoming pregnant.
  Talk to your healthcare provider about birth control choices while taking pioglitazone and metformin hydrochloride tablets. Tell your healthcare provider right away if you become pregnant while taking pioglitazone and metformin hydrochloride tablets
- **are breastfeeding or plan to breastfeed.** It is not known if pioglitazone and metformin hydrochloride passes into your milk and if it can harm your baby. Talk to your healthcare provider about the best way to control your blood glucose levels while breastfeeding

Tell your healthcare provider about all the medicines you take, including prescription and over the counter medicines, vitamins, and herbal supplements.
Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist before you start a new medicine. They will tell you if it is okay to take pioglitazone and metformin hydrochloride tablets with other medicines.
Pioglitazone and metformin hydrochloride tablets may affect the way other medicines work, and other medicines may affect how pioglitazone and metformin hydrochloride tablets works. Contact your healthcare provider before you start or stop other types of medicines.

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How should I take pioglitazone and metformin hydrochloride tablets?

- Take pioglitazone and metformin hydrochloride tablets exactly as your healthcare provider tells you to take it
- Your healthcare provider may need to change your dose of pioglitazone and metformin hydrochloride tablets. Do not change your pioglitazone and metformin hydrochloride tablets dose unless your healthcare provider tells you to
- Take pioglitazone and metformin hydrochloride tablets with meals to lower your chance of an upset stomach
- If you miss a dose of pioglitazone and metformin hydrochloride tablets, take your next dose as prescribed unless your healthcare provider tells you differently**. Do not take** two doses at one time the next day
- If you take too much pioglitazone and metformin hydrochloride tablets, call your healthcare provider 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 healthcare provider right away
- Stay on your diet and exercise programs and test your blood sugar regularly while taking pioglitazone and metformin hydrochloride tablets
- Your healthcare provider should do certain blood tests before you start and while you take pioglitazone and metformin hydrochloride tablets
- Your healthcare provider should also do hemoglobin A1C testing to check how well your blood sugar is controlled with pioglitazone and metformin hydrochloride tablets
- Your healthcare provider should check your eyes regularly while you take pioglitazone and metformin hydrochloride tablets

What are the possible side effects of pioglitazone and metformin hydrochloride tablets?
Pioglitazone and metformin hydrochloride tablets may cause serious side effects, including:

- **See "What is the most important information I should know about pioglitazone and metformin hydrochloride tablets?"**
- **Low blood sugar (hypoglycemia).** If you take pioglitazone and metformin hydrochloride tablets with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take pioglitazone and metformin hydrochloride tablets. Signs and symptoms of low blood sugar may include:
  - shaking or feeling jittery
  - change in vision
  - change in mood
  - sweating
  - hunger
  - confusion
  - fast heartbeat
  - headache
  - dizziness
- **Liver problems.** Call your healthcare provider right away or go to the nearest hospital emergency room 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
- **Bladder tumors.** There may be an increased chance of having bladder cancer when you take pioglitazone and metformin hydrochloride tablets. You should not take pioglitazone and metformin hydrochloride tablets if you are receiving treatment for bladder cancer. Tell your healthcare provider 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
- **Broken bones (fractures).** Usually in the hand, upper arm, or foot in women. Talk to your healthcare provider for advice on how to keep your bones healthy
- **Diabetic eye disease with swelling in the back of the eye (macular edema).** Tell your healthcare provider right away if you have any changes in your vision. Your healthcare provider 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 and metformin hydrochloride tablets. This can increase your chance of getting pregnant.
- **Low vitamin B_{12} (vitamin B_{12} deficiency).** Using metformin, one of the medicines in pioglitazone and metformin hydrochloride tablets for long periods of time may cause a decrease in the amount of vitamin B_{12} in your blood, especially if you have had low vitamin B_{12} levels before. Your healthcare provider may do blood tests to check your vitamin B_{12} levels**.** The most common side effects of pioglitazone and metformin hydrochloride tablets include:
  - cold-like symptoms (upper respiratory tract infection)
  - swelling (edema)
  - diarrhea
  - headache
  - increased weight

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the side effects of pioglitazone and metformin hydrochloride tablets. For more information, ask your healthcare provider 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 and metformin hydrochloride tablets?

- Store pioglitazone and metformin hydrochloride tablets at 20° to 25°C (68° to 77°F).
- Keep pioglitazone and metformin hydrochloride tablets in the original container and protect from light.
- Keep the pioglitazone and metformin hydrochloride tablets bottle tightly closed and keep tablets dry.

Keep pioglitazone and metformin hydrochloride tablets and all medicines out of the reach of children.

General information about the safe and effective use of pioglitazone and metformin hydrochloride tablets
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use pioglitazone and metformin hydrochloride tablets for a condition for which it was not prescribed. Do not give pioglitazone and metformin hydrochloride tablets to other people, even if they have the same symptoms you have. It may harm them.
You can ask your healthcare provider or pharmacist for information about pioglitazone and metformin hydrochloride tablets that is written for health professionals.

What are the ingredients in pioglitazone and metformin hydrochloride tablets?
Active Ingredients: pioglitazone hydrochloride and metformin hydrochloride
Inactive Ingredients: carboxymethylcellulose calcium, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol 6000, talc, and titanium dioxide.
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