

## Pioglitazone

### What is Pioglitazone?

Pioglitazone is used with a diet and exercise program and sometimes with other medications, to treat type 2 diabetes (condition in which the body's blood sugar is abnormally elevated). Pioglitazone is in a class of medications called thiazolidinediones (TZD's). It works by increasing the body's sensitivity to insulin, a natural substance that helps control blood sugar levels. This study involves the investigational use of pioglitazone to treat symptoms of major depression in patients with comorbid metabolic syndrome.

Pioglitazone is the active ingredient in the drug product ACTOS (pioglitazone) tablets. ACTOS has not been approved for the treatment of depression and its use in this study is experimental.

### What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:

- heart failure
- liver problems
- type I diabetes

### Side Effects

Along with its intended effects, a medicine may cause some unwanted effects. Below is a listing of side effects that have been associated with pioglitazone. Certain side effects have the potential to need medical attention.

You should immediately check with your doctor if you experience unexplained nausea, vomiting, abdominal pain, or dark urine. Rapid weight gain, swelling, shortness of breath, or other signs of heart failure should also be reported to your doctor.

In placebo controlled trials involving pioglitazone, the most common adverse events ( $\geq 5\%$ ) were:

upper respiratory tract infection;  
headache;  
sinusitis;  
muscle aches;  
tooth disorder;  
aggravation of diabetes;  
sore throat

Other potential side effects include:

fatigue;  
appetite loss;  
appetite increase;  
increased thirst;  
increased urination;

blurred vision;  
cough;  
dry skin;

Adequate contraception should be used for premenopausal women when taking pioglitazone. An increased incidence of bone fracture has been noted in women taking pioglitazone.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- rash
- difficulty breathing and wheezing
- a sudden drop in blood pressure
- swelling around the mouth, throat or eyes
- a fast pulse
- sweating

When taking any new medication, you should exercise caution and not drive, operate machinery, or engage in other activities requiring mental alertness until you know how the medication will affect you.