

## Patient Information

### ACTOPLUS MET<sup>®</sup> (ak-TŌ-plus-met)

#### (pioglitazone hydrochloride and metformin hydrochloride) tablets

Read the Patient Information that comes with ACTOPLUS MET 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. Always follow the directions given by your doctor.

### What is the most important information I should know about ACTOPLUS MET?

ACTOPLUS MET may cause or worsen congestive heart failure (“CHF”) in some people. Be sure and tell your doctor if you have congestive heart failure. People with the most serious form of congestive heart failure, called New York Heart Association Class III or IV should not start taking ACTOPLUS MET. If you have less serious congestive heart failure, called New York Heart Association Class I or II heart failure, your doctor will observe you carefully while taking ACTOPLUS MET. If you are taking ACTOPLUS MET and develop serious congestive heart failure, your doctor will decide whether you need to discontinue.

ACTOPLUS MET can **also** 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 ACTOPLUS MET and call your doctor right away if you get the following symptoms of lactic acidosis:

- You feel very weak or tired.
- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have stomach pain with nausea and vomiting, or diarrhea.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a slow or irregular heartbeat.
- Your medical condition suddenly changes.

**You have a higher chance for getting lactic acidosis with ACTOPLUS MET if you:**

- have kidney or liver problems
- have congestive heart failure that requires treatment with medicines
- drink a lot of alcohol (very often or 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 don't drink enough fluids.
- have certain x-ray tests with injectable dye used
- have surgery
- have a heart attack, severe infection, or stroke
- are 80 years of age or older and have not had your kidney function tested

## What is ACTOPLUS MET?

ACTOPLUS MET contains 2 prescription anti-diabetic medicines, pioglitazone hydrochloride (ACTOS<sup>®</sup>) and metformin (GLUCOPHAGE<sup>®</sup>) hydrochloride. ACTOPLUS MET is used with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes who are already taking pioglitazone hydrochloride (ACTOS) and metformin hydrochloride (GLUCOPHAGE) together or taking metformin hydrochloride (GLUCOPHAGE) alone and it is not controlling blood glucose at normal levels.

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 anti-diabetic medicines work better for you.

ACTOPLUS MET has not been studied in children and is not recommended for children.

## Who should not take ACTOPLUS MET?

**Do not take ACTOPLUS MET if you:**

- **have kidney problems**
- **have a condition called metabolic acidosis, including diabetic ketoacidosis.** Diabetic ketoacidosis should be treated with insulin.
- **are going to have an x-ray procedure with an injection of dyes.** Talk to your doctor about when to stop ACTOPLUS MET and when to start it again.
- **are allergic to pioglitazone hydrochloride (ACTOS) or metformin hydrochloride (GLUCOPHAGE).** See the end of this leaflet for a complete list of ingredients in ACTOPLUS MET.

## What should I tell my doctor before taking ACTOPLUS MET?

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

- **have heart problems, especially Class III/IV heart failure since ACTOPLUS Met can not be started with this condition**
- **have kidney problems**
- **have liver problems**
- **have a type of diabetic eye disease called macular edema** (swelling of the back of the eye).
- **are older than 80 years.** Patients over 80 years should not take ACTOPLUS MET unless their kidney function is checked and it is normal.
- **drink alcohol a lot** (all the time or short-term "binge" drinking)
- **are pregnant or planning to become pregnant.** It is not known if ACTOPLUS MET can harm your unborn baby. ACTOPLUS MET is not recommended for pregnant women. Talk to your doctor about the best way to control your blood glucose levels while pregnant.
- **are breastfeeding.** It is not known if ACTOPLUS MET passes into your milk and if it can harm your baby. You should not take ACTOPLUS MET if you breastfeed your baby. Talk to your doctor about the best way to control your blood glucose levels while breastfeeding.
- **are a premenopausal woman, who is not having periods regularly or at all, or a woman who has gone through the "change of life" (menopause).** ACTOPLUS MET can increase your chance of pregnancy. Talk to your doctor about effective birth control methods.

**Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements.** ACTOPLUS MET and some of your other medicines can interact with each other. You may need to have your dose of ACTOPLUS MET or certain other medicines adjusted. Certain other medicines can affect your blood glucose control. Know the medicines you take. Keep a list of them to show your doctor and pharmacist. Talk to your doctor before you start any new medicine.

## How should I take ACTOPLUS MET?

- Take ACTOPLUS MET exactly as prescribed. Your doctor will tell you how many ACTOPLUS MET tablets to take and how often you should take them. Your doctor may need to increase your dose to control your blood glucose. Do not change your dose unless told to do so by your doctor.
- Take ACTOPLUS MET with meals to lower your chance of an upset stomach.
- Stay on your diet and exercise programs and test your blood glucose regularly while taking ACTOPLUS MET.
- Your doctor should monitor your diabetes through regular blood tests. Your doctor should also do blood tests before starting ACTOPLUS MET and from time to time to check your liver, kidneys, and blood cells. Your doctor will also do a regular blood test called a hemoglobin A1C to check how well your blood sugar is controlled.
- If you miss a dose of ACTOPLUS MET take your next dose as prescribed unless your doctor tells you differently.
- If you take too much ACTOPLUS MET, call your doctor or poison control center right away.

### **You may need to stop ACTOPLUS MET for a short time. Call your doctor for instructions if you:**

- are sick with severe vomiting, diarrhea or fever, or if you drink a much lower amount of liquid than normal
- plan to have surgery
- are having an x-ray procedure with injection of dye

## What should I avoid while taking ACTOPLUS MET?

Do not drink a lot of alcohol while taking ACTOPLUS MET. This means you should not "binge drink" and you should not drink a lot of alcohol on a regular basis. Drinking a lot of alcohol can increase your chance of getting lactic acidosis.

## What are the possible side effects of ACTOPLUS MET?

- **Heart failure.** ACTOPLUS MET can cause your body to hold fluid. This can lead to heart failure or make heart failure you already have worse. Call your doctor right away if you have:
  - swelling in your ankles or legs
  - shortness of breath or trouble breathing, especially when you lie down
  - unusual tiredness
  - a sudden increase in weight
- **Lactic acidosis.** See, "What is the most important information I should know about ACTOPLUS MET?"
- **Hypoglycemia.** Call your doctor if you get lightheaded, dizzy, shaky or hungry. These can happen if you skip meals, use another medicine that lowers blood glucose, or if you have certain medical problems. Your dose of ACTOPLUS MET may need to be lowered if these symptoms are a problem for you.
- **Swelling (edema).** ACTOPLUS MET can cause your body to hold fluid and swell. This can be a problem for people who already have edema.

- **Weight gain.** This is probably due to swelling from extra fluid in your body and extra fat gain.
- **Liver problems.** In rare cases, ACTOPLUS MET may cause serious liver problems. Your doctor should do blood tests to check your liver before you start ACTOPLUS MET and regularly during treatment. Call your doctor right away if you get unexplained symptoms such as:
  - nausea or vomiting
  - stomach pain
  - unusual or unexplained tiredness
  - loss of appetite
  - dark urine
  - yellowing of your skin or whites of your eyes
- **Bone fractures.** Some people, particularly women, are at higher risk of having bone fractures while taking ACTOPLUS MET. Talk to your doctor for advice on how to keep your bones healthy.

**Some common side effects of ACTOPLUS MET** are diarrhea, nausea, and upset stomach. These side effects usually occur during the first few weeks of treatment. Taking ACTOPLUS MET with meals can help reduce these side effects. However, if you have unusual or unexpected stomach problems, talk with your doctor. Stomach problems that start up later during treatment may be a sign of something more serious.

Other common side effects of ACTOPLUS MET are cold-like symptoms, headache, and anemia.

These are not all the side effects of ACTOPLUS MET. For more information, ask your doctor or pharmacist.

## How should I store ACTOPLUS MET?

Store ACTOPLUS MET at room temperature in its original container.  
**Keep ACTOPLUS MET and all medicines out of the reach of children.**

## General information about ACTOPLUS MET

Medicines are sometimes prescribed for purposes other than those listed in the patient information leaflet. Do not use ACTOPLUS MET for a condition for which it is not prescribed. Do not share your medicine with other people even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about ACTOPLUS MET. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ACTOPLUS MET that is written for health care professionals. You can also get this "prescribing information" by visiting [www.actos.com](http://www.actos.com) or calling 1-877-825-3327.

## What are the ingredients in ACTOPLUS MET?

**Active Ingredients:** pioglitazone hydrochloride and metformin hydrochloride.

**Inactive Ingredients:** povidone USP, microcrystalline cellulose NF, croscarmellose sodium NF, magnesium stearate NF, hypromellose 2910 USP, polyethylene glycol 8000 NF, titanium dioxide USP, and talc USP.

**Rx Only**

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