MEDICATION GUIDE

Alogliptin and Pioglitazone Tablets

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

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

Alogliptin and pioglitazone tablets can cause serious side effects, including:

1. **Heart failure:** Alogliptin and pioglitazone tablets can cause heart failure and 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.

   Before you start taking alogliptin and pioglitazone tablets:

   Tell your doctor if you have ever had heart failure or have problems with your kidneys.

   Call your doctor right away if you have any of the following symptoms:
   - shortness of breath or trouble breathing, especially when you lie down
   - an unusually fast increase in weight
   - swelling or fluid retention, especially in the feet, ankles, or legs

   These may be symptoms of heart failure.
2. **Inflammation of the pancreas (pancreatitis):** Alogliptin, one of the medicines in alogliptin and pioglitazone tablets, may cause pancreatitis, which may be severe. Certain medical conditions make you more likely to get pancreatitis.

   Before you start taking alogliptin and pioglitazone tablets:

   Tell your doctor if you have ever had:

   - pancreatitis
   - kidney problems
   - liver problems

   Stop taking alogliptin and pioglitazone tablets and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

What are alogliptin and pioglitazone tablets?
- Alogliptin and pioglitazone tablets contain 2 prescription diabetes medicines, alogliptin (NESINA) and pioglitazone (ACTOS).
- Alogliptin and pioglitazone tablets are a prescription medicine used along with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes.
- Alogliptin and pioglitazone tablets are not for people with type 1 diabetes.
- Alogliptin and pioglitazone tablets are not for people with diabetic ketoacidosis (increased ketones in blood or urine).

It is not known if alogliptin and pioglitazone tablets are safe and effective in children under the age of 18. Alogliptin and pioglitazone tablets are not recommended for use in children.

Who should not take alogliptin and pioglitazone tablets?

Do not take alogliptin and pioglitazone tablets if you:

- have severe heart failure
- are allergic to alogliptin (NESINA), pioglitazone (ACTOS) or any ingredient in alogliptin and pioglitazone tablets or have had a serious allergic (hypersensitivity) reaction to alogliptin or pioglitazone. See the end of this Medication Guide for a complete list of the ingredients in alogliptin and pioglitazone tablets. Symptoms of a serious allergic reaction to alogliptin and pioglitazone 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 alogliptin and pioglitazone tablets and contact your doctor or go to the nearest hospital emergency room right away.

What should I tell my doctor before and during treatment with alogliptin and pioglitazone tablets?

Before you start taking alogliptin and pioglitazone tablets, tell your doctor if you:

- have heart failure
- have a type of diabetic eye disease that causes swelling of the back of the eye (macular edema)
- have kidney or liver problems
- have or have had inflammation of the pancreas (pancreatitis)
- have or have had cancer of the bladder
- have other medical conditions
- **are pregnant or plan to become pregnant.** It is not known if alogliptin and pioglitazone tablets can harm your unborn baby. Talk to your doctor about the best way to control your blood sugar while you are pregnant or if you plan to become pregnant.
- **are a premenopausal woman who does not have periods regularly or at all.** Alogliptin and pioglitazone tablets may increase your chance of becoming pregnant. Talk to your doctor about birth control choices while taking alogliptin and pioglitazone tablets. Tell your doctor right away if you become pregnant while taking alogliptin and pioglitazone tablets.
- **are breastfeeding or plan to breastfeed.** It is not known whether alogliptin and pioglitazone pass into your breast milk and if it can harm your baby. Talk with 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.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist before you start a new medicine.

Alogliptin and pioglitazone tablets may affect the way other medicines work, and other medicines may affect how alogliptin and pioglitazone tablets work. Contact your doctor before you start or stop other types of medicines.

How should I take alogliptin and pioglitazone tablets?

- Take alogliptin and pioglitazone tablets exactly as your doctor tells you to take it.
- Take alogliptin and pioglitazone tablets 1 time each day with or without food.
- Do not break or cut alogliptin and pioglitazone tablets before swallowing.
- Your doctor may need to change your dose of alogliptin and pioglitazone tablets to control your blood glucose. Do not change your dose unless told to do so by your doctor.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and take the next dose at your regular time. **Do not** take 2 doses of alogliptin and pioglitazone tablets at the same time.
- If you take too many alogliptin and pioglitazone tablets, call your doctor or go to the nearest hospital emergency room right away.

- If your body is under stress, such as from 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 check your blood sugar as your doctor tells you to.
- Your doctor may do certain blood tests before you start alogliptin and pioglitazone tablets and during treatment as needed. Your doctor may change your dose of alogliptin and pioglitazone tablets based on the results of your blood tests due to how well your kidneys are working.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.
- Your doctor should check your eyes regularly while you take alogliptin and pioglitazone tablets.

What are the possible side effects of alogliptin and pioglitazone tablets?

Alogliptin and pioglitazone tablets can cause serious side effects, including:

- See "**What is the most important information I should know about alogliptin and pioglitazone tablets?**"
- **Allergic (hypersensitivity) reactions,** such as:
  - swelling of your face, lips, throat and other areas on your skin
  - raised, red areas on your skin (hives)
  - difficulty swallowing or breathing
  - skin rash, itching, flaking or peeling

  If you have these symptoms, stop taking alogliptin and pioglitazone tablets and contact your doctor right away.
- **Liver problems.** Call your doctor right away if you have unexplained symptoms such as:
  - nausea or vomiting
  - loss of appetite
  - stomach pain
  - dark urine
  - unusual or unexplained tiredness
  - yellowing of your skin or the whites of your eyes
- **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.
- **Bladder cancer.** There may be an increased chance of having bladder cancer when you take alogliptin and pioglitazone tablets. You should not take alogliptin and 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 a red color in your urine
  - an increased need to urinate
  - pain while you urinate
- **Low blood sugar (hypoglycemia).** If you take alogliptin and pioglitazone 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 alogliptin and pioglitazone tablets. If you have symptoms of low blood sugar, you should check your blood sugar and treat if low, then call your doctor. Signs and symptoms of low blood sugar may include:
  - shaking or feeling jittery
  - headache
  - sweating
  - change in mood
  - fast heartbeat
  - confusion
  - change in vision
  - dizziness
  - hunger
- **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 alogliptin and pioglitazone tablets. This can increase your chance of getting pregnant.
- **Joint pain.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in alogliptin and pioglitazone tablets, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.
- **Skin reaction.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in alogliptin and pioglitazone tablets, may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your doctor right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your doctor may tell you to stop taking alogliptin and pioglitazone tablets.

The most common side effects of alogliptin and pioglitazone tablets include stuffy or runny nose and sore throat, back pain, cold-like symptoms (upper respiratory tract infection).

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of alogliptin and 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 alogliptin and pioglitazone tablets?

- Store alogliptin and pioglitazone tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep container tightly closed and protect from moisture and humidity.

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

General information about the safe and effective use of alogliptin and pioglitazone tablets

Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not take alogliptin and pioglitazone tablets for a condition for which it was not prescribed. Do not give alogliptin and pioglitazone tablets to other people, even if they have the same symptoms you have. They may harm them.

This Medication Guide summarizes the most important information about alogliptin and pioglitazone tablets. If you would like to know more information, talk with your doctor. You can ask your doctor or pharmacist for information about alogliptin and pioglitazone tablets that is written for health professionals.

For more information, go to www.perrigo.com or call 1-877-TAKEDA-7 (1-877-825-3327).

What are the ingredients in alogliptin and pioglitazone tablets?

Active ingredients: alogliptin and pioglitazone.

Inactive ingredients: mannitol, microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium, magnesium stearate, and lactose monohydrate; the tablets are film-coated with hypromellose, polyethylene glycol, titanium dioxide, talc and ferric oxide (yellow and/or red) and are marked with red A1 or gray F1 printing ink.

Distributed By
Perrigo®
Allegan, MI 49010 • www.perrigo.com

All trademarks are the property of their respective owners

ALS333 R3

This Medication Guide has been approved by the U.S. Food and Drug Administration.
12/2016