

MEDICATION GUIDE Alogliptin and Metformin HCl Tablets

Read this Medication Guide carefully before you start taking alogliptin and metformin HCl 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 treatment. If you have any questions about alogliptin and metformin HCl tablets, ask your doctor or pharmacist.

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

Alogliptin and metformin HCl tablets can cause serious side effects, including:

- Lactic Acidosis. Metformin, one of the medicines in alogliptin and metformin HCl 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.**

Call your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you feel sleepy or drowsy
- you have stomach pains, nausea or vomiting

Most people who have had lactic acidosis with metformin have other things that, combined with metformin, led to the lactic acidosis. Tell your doctor if you have any of the following, because you have a higher chance for getting lactic acidosis with alogliptin and metformin HCl 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

The best way to keep from having a problem with lactic acidosis from metformin is to tell your doctor if you have any of the problems listed above. You doctor may decide to stop alogliptin and metformin HCl tablets for a while if you have any of these things.

Alogliptin and metformin HCl tablets can have other serious side effects. See “What are the possible side effects of alogliptin and metformin HCl tablets?”

- Inflammation of the pancreas (pancreatitis).** Alogliptin, one of the medicines in alogliptin and metformin HCl tablets, may cause pancreatitis, which may be severe. Certain medical conditions make you more likely to get pancreatitis.

Before you start taking alogliptin and metformin HCl tablets:

Tell your doctor if you have ever had:

- pancreatitis
- kidney problems
- liver problems

Stop taking alogliptin and metformin HCl 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.

3. Heart failure:

Before you start taking alogliptin and metformin HCl tablets:

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

Contact your healthcare provider right away if you have any of the following symptoms:

- increasing shortness of breath or trouble breathing especially when lying down
- an unusually fast increase in weight
- swelling of feet, ankles, or legs

These may be symptoms of heart failure.

What are alogliptin and metformin HCl tablets?

- Alogliptin and metformin HCl tablets contain 2 prescription diabetes medicines, alogliptin (NESINA) and metformin hydrochloride.
- Alogliptin and metformin HCl 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 metformin HCl tablets are not for people with type 1 diabetes.
- Alogliptin and metformin HCl tablets are not for people with diabetic ketoacidosis (increased ketones in blood or urine).

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

Who should not take alogliptin and metformin HCl tablets?

Do not take alogliptin and metformin HCl tablets if you:

- have severe kidney problems
- have a condition called metabolic acidosis or have had diabetic ketoacidosis (increased ketones in your blood or urine)
- are going to get an injection of dye or contrast agents for an x-ray procedure, alogliptin and metformin HCl tablets may need to be stopped for a short time. Talk to your doctor about when you should stop alogliptin and metformin HCl tablets and when you should start alogliptin and metformin HCl tablets again
- are allergic to alogliptin or metformin or any of the ingredients in alogliptin and metformin HCl tablets or have had a serious allergic (hypersensitivity) reaction to alogliptin or metformin. See the end of this Medication Guide for a complete list of the ingredients in alogliptin and metformin HCl tablets

Symptoms of a serious allergic reaction to alogliptin and metformin HCl 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 any of these symptoms, stop taking alogliptin and metformin HCl 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 metformin HCl tablets?

Before you take alogliptin and metformin HCl tablets, tell your doctor if you:

- have or have had inflammation of your pancreas (pancreatitis)
- have severe kidney or liver problems
- have heart problems, including congestive heart failure
- are going to get an injection of dye or contrast agents for an x-ray procedure, alogliptin and metformin HCl tablets may need to be stopped for a short time. Talk to your doctor about when you should stop alogliptin and metformin HCl tablets and when you should start alogliptin and metformin HCl tablets again
- drink alcohol very often or drink a lot of alcohol in short-term “binge” drinking
- have other medical conditions
- are pregnant or plan to become pregnant. It is not known if alogliptin and metformin HCl tablets will harm your unborn baby. Talk with your doctor about the best way to control your blood sugar while you are pregnant or if you plan to become pregnant
- are breastfeeding or plan to breastfeed. It is not known whether alogliptin and metformin pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking alogliptin and metformin HCl tablets

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 any new medicine.

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

How should I take alogliptin and metformin HCl tablets?

- Take alogliptin and metformin HCl tablets exactly as your doctor tells you to take it.
- Take alogliptin and metformin HCl tablets 2 times each day.
- Take alogliptin and metformin HCl tablets with food to lower your chances of having an upset stomach.
- Do not break or cut alogliptin and metformin HCl tablets before swallowing.
- Your doctor may need to change your dose of alogliptin and metformin HCl 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 metformin HCl tablets at the same time.
- If you take too many alogliptin and metformin HCl 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 metformin HCl tablets and during treatment as needed. Your doctor may ask you to stop taking alogliptin and metformin HCl 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.

What are the possible side effects of alogliptin and metformin HCl tablets?

Alogliptin and metformin HCl tablets can cause serious side effects, including:

- See “**What is the most important information I should know about alogliptin and metformin HCl 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 peelingIf you have these symptoms, stop taking alogliptin and metformin HCl 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

- **Low blood sugar (hypoglycemia).** If you take alogliptin and metformin HCl 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 metformin HCl tablets. If you have symptoms of low blood sugar, you should check your blood sugar and treat if low, and then call your doctor. Signs and symptoms of low blood sugar may include:

- shaking or feeling jittery
- sweating
- fast heartbeat
- hunger
- change in mood
- dizziness
- change in vision
- headache
- confusion

- **Joint pain.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in alogliptin and metformin HCl 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 metformin HCl 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 metformin HCl tablets.

The most common side effects of alogliptin and metformin HCl tablets include:

- cold-like symptoms (upper respiratory tract infection)
- increase in blood pressure
- urinary tract infection
- stuffy or runny nose and sore throat
- diarrhea
- headache
- back pain

Taking alogliptin and metformin HCl tablets with food can help lessen the common stomach side effects of metformin that usually happen at the beginning of treatment. If you have unexplained stomach problems, tell your doctor. Stomach problems that start later, during treatment, may be a sign of something more serious.

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 metformin HCl 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 metformin HCl tablets?

- Store alogliptin and metformin HCl tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the container of alogliptin and metformin HCl tablets tightly closed.

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

General information about the safe and effective use of alogliptin and metformin HCl tablets

Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not take alogliptin and metformin HCl tablets for a condition for which it was not prescribed. Do not give alogliptin and metformin HCl 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 metformin HCl 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 metformin HCl 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 metformin HCl tablets?

Active ingredients: alogliptin and metformin hydrochloride

Inactive ingredients: mannitol, microcrystalline cellulose, povidone, crospovidone and magnesium stearate; the tablets are film-coated with hypromellose 2910, talc, titanium dioxide and ferric oxide yellow.

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

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