

ZEMIGLO 50 MG FILM-COATED TABLET

Gemigliptin (50mg)

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What Zemiglo is used for

Zemiglo contains the active substance gemigliptin which is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) that lowers blood sugar levels in adult patients with type 2 diabetes mellitus.

Your doctor has prescribed this medicine to help lower your blood sugar, which is too high because of your type 2 diabetes. This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or dapagliflozin) that lower blood sugar, which you may already be taking for your diabetes.

How Zemiglo works

This medicine helps to increase the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

Before you use Zemiglo

- When you must not use it

Do not take this medicine if:

- you are allergic to gemigliptin or any other ingredients of this medicine.

- Before you start to use it

Tell your doctor if you:

- have type 1 diabetes
- have diabetic ketoacidosis (increased ketones in the blood or urine)
- have any kidney problems, or any past or present medical problems
- have an allergic reaction to Zemiglo
- have symptoms of pancreatitis (persistent, severe abdominal pain)
- are pregnant, planning for pregnancy or breast-feeding

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any of the following:

- metformin, pioglitazone, glimepiride, dapagliflozin, empagliflozin (treatment for diabetes)
- rosuvastatin (treatment for high cholesterol level)
- ketoconazole (to treat fungus or yeast infections)
- rifampicin (to treat bacterial infections)

How to use Zemiglo

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults:

The recommended dose is to take:

- one 50 mg tablet
- once a day
- by mouth, with or without food

If you have kidney problems, your doctor may prescribe lower doses.

Your doctor may prescribe this medicine alone or with certain other medicines that lower blood sugar.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use Zemiglo for the duration that the doctor recommends.

Diet and exercise can help your body use its blood sugar better. It is important to stay on your doctor recommended diet, exercise and weight loss program while taking Zemiglo.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Zemiglo.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Zemiglo to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Acute pancreatitis

Cases of inflammation of the pancreas (pancreatitis) have been reported in

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patients receiving Zemiglo. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking Zemiglo and call your doctor if you experience severe and persistent stomach pain, with or without vomiting, because you could have pancreatitis.

Bullous pemphigoid

Cases of a skin reaction called bullous pemphigoid that can require treatment in a hospital have been reported in patients receiving DPP-4 inhibitors. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking Zemiglo.

Hypersensitive reaction

Cases of severe hypersensitivity reactions including Stevens-Johnson syndrome have been reported in patients receiving Zemiglo. If a severe hypersensitivity reaction is suspected, your doctor may tell you to stop taking Zemiglo, and alternative treatment should be started.

Severe and disabling arthralgia

Cases of severe and disabling arthralgia have been reported in patients receiving DPP-4 inhibitors. Tell your doctor if you develop symptoms of severe and disabling arthralgia. Your doctor may tell you to stop taking Zemiglo.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause hypoglycaemia, which may affect your ability to drive and use machines or work without safe foothold.

Side effects

Like all medicines, Zemiglo can cause side effects, although not everybody gets them.

The following side effects have been reported:

- *Gastrointestinal disorders*: Indigestion,

constipation, diarrhea, nausea, abdominal pain upper, gastric disorder, burping, bleeding in stomach, high level of acid in stomach

- *General disorders and administration site conditions*: Swelling
- *Infections and infestations*: High level of bacteria in urine, inflammation of the nasal passages, upper respiratory tract infection, urinary tract infection
- *Investigations*: Blood creatine increased, abnormal liver function test, pancreatic enzyme increased, weight decreased, weight increased
- *Metabolism and nutrition disorders*: Low blood sugar with symptoms, high level of fat in blood
- *Musculoskeletal and connective tissue disorders*: Joint pain, muscle pain
- *Nervous system disorders*: Dizziness, headache
- *Psychiatric disorders*: Sleeping difficulty
- *Respiratory, thoracic and mediastinal disorders*: Nose bleeding, pneumonia
- *Skin and subcutaneous tissue disorders*: Dermatitis, photosensitivity reaction, itchy skin, rash, hives

If any of the following happens, stop taking Zemiglo and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Stevens Johnson syndrome: Severe blistering or peeling of the skin; bleeding in the lips, eyes, mouth, nose and genitals; swelling around the eyes, lips and face, rashes caused by exposure to sunlight.
- Pancreatitis: Inflammation of the pancreas. Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website

npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Zemiglo

- *Storage*

Keep out of the reach and sight of children.

Store below 30°C in tight container.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Lemon type, orange colored, film-coated tablet, debossed with LG symbol and a wave pattern on one side and a parting line on the other.

- *Ingredients*

- Active ingredient
Gemigliptin, 50mg.
- Inactive ingredients
 - Microcrystalline Cellulose (Type 102)
 - Microcrystalline Cellulose (Type 101)
 - Croscarmellose Sodium
 - Stearyl Fumarate Sodium
 - Opadry II 85F43172
 - Polyvinyl Alcohol
 - Titanium Dioxide
 - Polyethylene Glycol 3350
 - Talc
 - FD&C Yellow #6 Sunset Yellow FCF Aluminum Lake
 - Red Iron Oxide

- *MAL number:*

MAL25106001AZ

Manufacturer

LG Chem, Ltd.

151, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea.

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Product Registration Holder

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15/4/2025.

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