ZEMIDAPA 50/10MG FILM COATED TABLET

Gemigliptin tartrate sesquihydrate/Dapagliflozin amorphous (50mg per 10mg)

What is in this leaflet

1. What Zemidapa is used for
2. How Zemidapa works
3. Before you use Zemidapa
4. How to use Zemidapa
5. While you are using it
6. Side effects
7. Storage and Disposal of Zemidapa
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What Zemidapa is used for

Zemidapa contains two active ingredients, gemigliptin tartrate sesquihydrate and dapagliflozin amorphous. Gemigliptin tartrate sesquihydrate belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors) and dapagliflozin amorphous belongs to a class of medicine called SGLT 2 (sodium glucose cotransporter-2) inhibitors. This medicine is used if you type 2 diabetes mellitus cannot be controlled with other oral diabetes medicines, along with diet and exercise.

Type 2 diabetes mellitus

Type 2 diabetes mellitus 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 and can lead to serious medical problems.

The main goal of treating type 2 diabetes is to control your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness and amputation.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why Zemidapa has been prescribed for you.

Zemidapa is not addictive.

How Zemidapa works

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

Before you use Zemidapa

- *When you must not use it*

  Do not take this medicine if you:
  - allergic to gemigliptin tartrate sesquihydrate and dapagliflozin amorphous or any other ingredients of this medicine (listed in Product Description)
  - have poorly functioning kidneys, severe kidney disease or kidney failure. Zemidapa requires good functioning kidneys to work well.
  - have poor liver function or severe liver failure. If you have or have had problems with your liver, tell your doctor before take any Zemidapa.

  Zemidapa is not recommended for use in children. It has not been studies in children younger than 18 years old.

- *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 a rare hereditary problems of galactose intolerance, total lactose deficiency or glucose-galactose malabsorption
  - undergoing hemodialysis treatment

  Pregnancy and lactation

  Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

  Do not take this medicine if you are pregnant or plan to become pregnant. The safety of Zemidapa in pregnant women has not been established. Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Zemidapa with insulin while you are pregnant.

  Do not take Zemidapa if you are breastfeeding. Zemidapa is not recommended while you are breastfeeding. Your doctor will discuss the options available to you.

  Discard any other medicines containing gemigliptin tartrate sesquihydrate or dapagliflozin amorphous that your doctor might have prescribed to you in the past and that you may still have in your possession. If you have more than one medicine containing dapagliflozin amorphous or gemigliptin tartrate sesquihydrate in your possession, you may accidentally take too much (overdose).

  Ask your doctor or pharmacist if you are unsure if you have any other medicines containing dapagliflozin amorphous or gemigliptin tartrate sesquihydrate. Your doctor or pharmacist will know which other medicines also contain gemigliptin tartrate sesquihydrate and dapagliflozin amorphous and can tell you what to do.

- *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.

  You should tell your doctor if you are taking the following medicine as it may interact with Zemidapa:
  - lithium because Zemidapa can lower the amount of lithium in your blood
  - metformin, pioglitazone, glimepiride, dapagliflozin amorphous and empagliflozin (treatment for diabetes)
  - rosuvastatin (treatment for high cholesterol level)
  - ketoconazole (to treat fungus or yeast infection)
  - rifampicin (to treat bacterial infection)
  - diuretics (to treat high blood pressure)

ZEMIDAPA 50/10MG FILM COATED TABLET

Gemigliptin tartrate sesquihydrate/Dapagliflozin amorphous (50mg per 10mg)

How to use Zemidapa

- *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. The recommended dose is one tablet daily.

  Zemidapa can be taken orally once daily 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 Zemidapa 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 Zemidapa.

- *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 use 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 Zemidapa.

  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 Zemidapa 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 patients receiving Zemidapa. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking Zemidapa 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 Zemidapa.

  Hypersensitivity reaction

  Cases of severe hypersensitivity reactions including Stevens-Johnson syndrome have been reported in patients receiving Zemidapa. If a severe hypersensitivity reaction is suspected, your doctor may tell you to stop taking Zemidapa, 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 Zemidapa.

  Hypoglycemia

  Cases of hypoglycemia have been reported in patients receiving Zemidapa in combination with a sulfonylurea or with insulin. A reduction in the dose of sulfonylurea or insulin may be necessary.

  Urosepsis and pyelonephritis

  Cases of serious urinary tract infections have been reported in patient receiving Zemidapa. Stop taking Zemidapa and call your doctor if you have signs and symptoms of urinary tract infection.

  Lower limb amputation

  Cases of lower limb amputation have been observed in long-term usage of Zemidapa. It is important to practice routine preventive foot care.

  Fourier's gangrene (bacterial infection at genital area)

  Cases of Fourier's gangrene have been reported in patient receiving Zemidapa. Fourier's gangrene is serious and potentially life-threatening that requires urgent surgical and antibiotic treatment. Stop taking Zemidapa and call your doctor if you experience pain, tenderness, rash or swelling in the genital or perineal area, with a fever or discomfort.

  Cardiac impairment

  There are limited clinical experience in patient for cardiac status with Zemidapa. Zemidapa should be used with caution in this population.

  Genital mycotic infections

  Zemidapa increased the risk of genital myotic infections. It is important to monitor and treat appropriately.

  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 hypoglycemia, which may affect your ability to drive and use machines or work without safe foothold.

ZEMIDAPA 50/10MG FILM COATED TABLET

Gemigliptin tartrate sesquihydrate/Dapagliflozin amorphous (50mg per 10mg)

Side effects

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

Seek immediate medical attention when symptoms such as nausea, vomiting, decreased appetite, abdominal pain, excessive thirst, difficulty in breathing, confusion, unusual fatigue or sleepiness, frequent urination and fruity-smelling breath occur.

The following side effects have been reported:

- *Investigation:* Acute pancreatitis, liver inflammation, liver damage, weight decreased, and blood creatine increased
- *Gastrointestinal disorders:* Chronic gastritis, growth (polyp) in the lining of colon, indigestion, constipation, gastroesophageal reflux disease (GERD) and nausea
- *Infections and infestations:* Urinary tract infection, gum inflammation, Covid-19 infection, inflammation of bladder, common cold and upper respiratory tract infection
- *Nervous system disorder:* Dizziness and headache
- *Respiratory, thoracic and mediastinal disorders:* Cough
- *Renal and urinary disorders:* Kidney damage or failure, blood in urine and frequent urination
- *Skin and subcutaneous tissue disorder:* Itching and rash
- *Metabolism and nutrition disorders:* Hypoglycemia (low blood sugar levels)
- *Musculoskeletal and connective tissue disorders:* Muscles pain, back pain, extreme pain and joint pain
- *Reproductive system and breast disorders:* Pruritus and inflammation at virginal area
- *Psychiatric disorders:* Sleeping difficulty
- *General disorders and administration site conditions:* Chest pain
- *Hepatobiliary disorders*: Fatty liver disease

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

- Signs of hypoglycemia (low blood sugar) may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, rapid heartbeat, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers. Do not drive a car if you have signs of low blood sugar.

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 Zemidapa

- *Storage*

  Keep out of the reach and sight of children.

  Store below 30°C. Store in tight container. Do not freeze.

  Store in the originally container. Placing in container other that the ones provided by the manufacturer may lead to drug misuse or affect the quality of the drug product.

- *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*

  Zemidapa is round, bright brown film coated tablet, debossed with LG symbol and a wave pattern on one side and a parting line on the other.

- *Ingredients*
  - Active ingredient(s)

    50mg of gemigliptin tartrate sesquihydrate and 10mg of dapagliflozin amorphous
  - Inactive ingredients

    Microcrystalline Cellulose (Type 102), Lactose Anhydrous, Croscarmellose Sodium, Sodium Stearyl Fumarate, Opadry II 85F665000 Brown, Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol 3350, Talc, Yellow Iron Oxide and Red Iron Oxide

- *MAL number(s):*

  MAL25106002AZ

Manufacturer

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

Product Registration Holder

Pharmaniaga Marketing Sdn Bhd
No 7, Lorong Keluli 1B, Kawasan
Perindustrian, Bukit Raja Selatan,
Seksyen 7, 40000 Shah Alam,
Selangor Darul Ehsan,
Malaysia.

Date of revision

23/6/2025

Serial Number

NPRA (R1) 25/017