

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

**PrGlyxambi™**  
empagliflozin and linagliptin tablets

*Read this carefully before you start taking GLYXAMBI and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about GLYXAMBI.*

**Serious Warnings and Precautions**

- **Diabetic ketoacidosis (DKA)** is a serious and life-threatening condition that requires urgent hospitalization. DKA has been reported in patients with type 2 diabetes with normal or high blood sugar levels who are treated with empagliflozin (one of the medicines in GLYXAMBI) and other sodium-glucose co-transporter 2 (SGLT2) inhibitors. Some cases of DKA have led to death.
- Seek medical attention right away and **stop taking GLYXAMBI immediately** if you have any of the following symptoms (even if your blood sugar levels are normal): difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusually tired, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat.

Do not use GLYXAMBI if you have:

- DKA or a history of DKA;
- type 1 diabetes.

**What is GLYXAMBI used for?**

GLYXAMBI is used with metformin along with diet and exercise, to improve blood sugar levels in adults with type 2 diabetes. GLYXAMBI can be used:

- in patients who are not controlled with metformin and JARDIANCE (empagliflozin), or
- in patients who are not controlled with metformin and TRAJENTA (linagliptin), or
- in patients currently taking metformin and JARDIANCE (empagliflozin), and TRAJENTA (linagliptin) as separate tablets.

**How does GLYXAMBI work?**

GLYXAMBI contains two medicines: empagliflozin and linagliptin.

Empagliflozin belongs to a class of medicines called sodium-glucose co-transporter 2 (SGLT2) inhibitors. It removes excess sugar from the body through the urine.

Linagliptin belongs to a class of medicines called dipeptidyl peptidase-4 (DPP-4) inhibitors. It helps to improve insulin levels in the body when blood sugar levels are high, especially after a meal.

Linagliptin also helps to decrease the amount of sugar made by the body.

**What are the ingredients in GLYXAMBI?**

Medicinal ingredients: empagliflozin and linagliptin.

Non-medicinal ingredients: copovidone, corn starch, crospovidone, hypromellose, magnesium stearate, mannitol, polyethylene glycol, pregelatinized starch, talc and titanium dioxide.

**GLYXAMBI comes in the following dosage forms:**

Tablets containing:

- 10 mg empagliflozin and 5 mg linagliptin, or
- 25 mg empagliflozin and 5 mg linagliptin.

**Do not use GLYXAMBI if you:**

- are allergic to any of the ingredients in GLYXAMBI including empagliflozin (or any other SGLT2 inhibitor) and linagliptin (or any other DPP-4 inhibitor);
- have severe kidney problems or are on dialysis;
- have DKA;
- have type 1 diabetes;
- are experiencing loss of fluids from the body due to vomiting, diarrhea or dehydration;
- are pregnant or are planning on becoming pregnant;
- are breastfeeding or are planning to breastfeed; or
- are under 18 years of age.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take GLYXAMBI. Talk about any health conditions or problems you may have, including if you:**

- have an increased chance of developing DKA, including if you:
  - are dehydrated or suffer from excessive vomiting, diarrhea, or sweating;
  - are on a very low carbohydrate diet;
  - drink a lot of alcohol;
  - have/have had problems with your pancreas, including pancreatitis or surgery on your pancreas;
  - are hospitalized for major surgery, serious infection or serious medical illnesses;
  - have a history of DKA.
- have kidney problems;
- have liver problems;
- have heart failure or heart disease;
- are at high risk for stroke (e.g. due to heart rhythm problems, history of mini-strokes etc.);
- have low blood pressure;
- are taking a medicine for high blood pressure or taking a water pill (used to remove excess water from the body);
- are taking insulin. Taking GLYXAMBI with insulin can increase the risk of having low blood sugar (hypoglycemia). GLYXAMBI is not approved for use with insulin;

- are taking other medicines to lower your blood sugar. Taking GLYXAMBI with these medicines can increase the risk of having low blood sugar (hypoglycemia);
- have been told by a doctor that you have a reduced immune system. For example, if you have had organ transplantation or if you have HIV/AIDS;
- have a history of yeast infection of the vagina or penis. GLYXAMBI increases your chance of getting a yeast infection. This is more likely if you have had an infection in the past;
- have or have had inflammation of your pancreas (pancreatitis);
- have a history of urinary tract infections or problems with urination;
- have any skin problems;
- are 65 years of age or older. If you are older than 75 years of age, the use of GLYXAMBI is not recommended.

**Other warnings you should know about:**

Your blood sugar may get too high (hyperglycemia) if you have fever, infection, surgery or trauma (stress conditions). In such cases, contact your doctor as your medication may need to be adjusted.

GLYXAMBI may cause dizziness or light-headedness. Do not drive or use machines until you know how the medicine affects you.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with GLYXAMBI:**

- some medicines, including insulin, that are used to treat diabetes;
- medicines used to treat seizures such as phenobarbital, carbamazepine and phenytoin may require that your doctor monitor control of your blood sugar levels more closely;
- rifampin (used to treat bacterial infections), dexamethasone (a steroid), may require that your doctor monitor control of your blood sugar levels more closely;
- medicines to lower your blood pressure;
- diuretics, known as water pills, such as furosemide. They are used to remove excess water from the body;
- an herbal medicine called St. John's Wort, which may reduce the effect of GLYXAMBI.

**How to take GLYXAMBI:**

Follow the directions given to you by your doctor.

Take GLYXAMBI:

- once a day;
- at any time of the day, at about the same time each day;
- by mouth;
- with or without food.

Swallow whole. Do NOT cut or divide tablets.

**Usual dose:**

GLYXAMBI comes in two strengths: 10 mg/5 mg tablets and 25 mg/5 mg tablets. Your doctor will tell you which strength of GLYXAMBI to start with. GLYXAMBI should be taken as one tablet once a day.

**Overdose:**

If you think you have taken too much GLYXAMBI, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

- If it is 12 hours or more until your next dose, take GLYXAMBI as soon as you remember. Then take your next dose at the usual time.
- If it is less than 12 hours until your next dose, skip the missed dose. Then take your next dose at the usual time.
- Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

**What are possible side effects from using GLYXAMBI?**

These are not all the possible side effects you may have when taking GLYXAMBI. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- cough (with or without phlegm);
- stuffy or runny nose;
- sore throat;
- mouth ulcers;
- diarrhea;
- nausea and vomiting;
- abdominal pain;
- constipation;
- weight loss;
- headache/dizziness;
- back pain;
- joint pain;
- muscle pain;
- feeling weak;
- tremor;
- passing more urine than usual or needing to pass urine more often;
- strain or pain when urinating;
- itchiness;
- rash.

**If any of the above affect you severely, tell your doctor or pharmacist.**

GLYXAMBI can cause abnormal blood test results. Your doctor will decide when to perform blood tests. They may check kidney function, liver function, blood fat levels and amount of red blood cells in your blood (hematocrit).

**DKA is a serious medical condition normally seen at high blood sugar levels; however, it has also been seen at near normal blood sugar levels. Get immediate medical help if you have any of the symptoms described in the table below under DKA, even if your blood glucose levels are normal.**

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Urinary tract infection:</b> burning sensation when passing urine, pain in the pelvis or mid-back pain, increased need to urinate.		✓	
<b>Low blood sugar (hypoglycemia):</b> shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.		✓	
<b>Genital infections:</b> Vaginal yeast infection: severe itching, burning, soreness, irritation and a whitish-grey cottage cheese-like discharge.  Yeast infection of the penis: red, swollen, itchy head of the penis; thick, lumpy discharge under foreskin with an unpleasant odour; difficulty retracting foreskin, pain when passing urine or during sex.	✓		
<b>UNCOMMON</b>			
<b>Volume depletion (loss of fluids from the body, dehydration especially in patients older than 75 years of age):</b> dry or sticky mouth, headache, dizziness, urinating less often than normal, thirst, feeling faint, light-headed or			✓

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
weak, especially when standing up.			
<b>Allergic (hypersensitivity) reactions:</b> hives, swelling of the face, lips, tongue and throat that may cause difficulty in breathing or swallowing; wheezing and shortness of breath.			✓
<b>Low blood pressure:</b> dizziness, fainting, light-headedness. May occur when you go from lying down to sitting or standing up.		✓	
<b>Kidney problems:</b> any change in the amount, frequency or colour (pale or dark) of urine.		✓	
<b>Sepsis (severe infection that spreads from urinary tract throughout body):</b> fever or low body temperature, chills, rapid breathing, rapid heartbeat, pain with urination, difficulty urinating, frequent urination.			✓
<b>Acute kidney infection:</b> painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul smelling urine, blood in the urine.			✓
<b>Pancreatitis (inflammation of the pancreas):</b> prolonged severe abdominal pain which may be accompanied by vomiting.			✓
<b>UNKNOWN</b>			
<b>Diabetic ketoacidosis (DKA):</b> difficulty breathing, feeling very thirsty, vomiting, stomach pain, nausea, loss of appetite, confusion, unusual tiredness, a sweet smell to the breath, a sweet or metallic taste in the mouth, a different odour to			✓

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
urine or sweat.			
<b>Severe skin reactions:</b> skin rashes, redness, peeling skin, and/or blistering of the skin, lips, eyes or mouth.			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

Store at 15-30°C.

Keep out of reach and sight of children.

**If you want more information about GLYXAMBI:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer’s website (<http://www.boehringer-ingelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, extension 84633.

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