

1-2-3 TALK GLYXAMBI

A talk with your doctor is the best way to find out how GLYXAMBI adds up. And starting the conversation is as quick as 1-2-3.

Getting the conversation started is as quick as...

1

Is there a once-daily medication that works in multiple ways that will help me manage my type 2 diabetes?

2

Is there a medication that offers the power of 2 proven diabetes medicines working together to lower A1C and blood sugar?

3

What's the connection between cardiovascular disease and type 2 diabetes?

Want to know more? Here's a look at how GLYXAMBI adds up.

ONE daily pill taken in the morning along with diet and exercise—GLYXAMBI brings together the power of...

TWO proven diabetes medicines—JARDIANCE (empagliflozin) and TRADJENTA (linagliptin) combined as GLYXAMBI.

Working together along with diet and exercise, GLYXAMBI can help lower A1C. And in adults with type 2 diabetes who also have known heart disease, JARDIANCE, one of the medicines in GLYXAMBI, can reduce the risk of cardiovascular death. While JARDIANCE has been shown to reduce the risk of cardiovascular death, the effectiveness of GLYXAMBI, the combination of JARDIANCE and TRADJENTA, on reducing the risk of cardiovascular death has not been studied. These medications work with the body in...

THREE ways to lower blood sugar and A1C.

⊕ Increases insulin production ⊖ Decreases sugar production ⬇ Removes some sugar

Talk to your doctor about the type 2 diabetes medicine that works in multiple ways.

What is GLYXAMBI?

GLYXAMBI is a prescription medication containing two medicines, empagliflozin (JARDIANCE) and linagliptin (TRADJENTA). GLYXAMBI can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes, and can be used in adults with type 2 diabetes who have known cardiovascular disease when both empagliflozin and linagliptin are appropriate and empagliflozin is needed to reduce the risk of cardiovascular death. The effectiveness of GLYXAMBI at reducing the risk of cardiovascular death has not been studied.

GLYXAMBI is not for people with type 1 diabetes or for diabetic ketoacidosis (increased ketones in the blood or urine). If you have had pancreatitis (inflammation of the pancreas) it is not known if you have a higher chance of getting pancreatitis while taking GLYXAMBI.

SELECTED SAFETY INFORMATION

Do not take GLYXAMBI if you have severe kidney problems or are on dialysis.

Do not take GLYXAMBI if you are allergic to linagliptin (TRADJENTA), empagliflozin (JARDIANCE), or any of the ingredients in GLYXAMBI.

Serious side effects can happen to people taking GLYXAMBI, including:

• **Inflammation of the pancreas (pancreatitis)**, which may be severe and lead to death. Before you start taking GLYXAMBI, tell your doctor if you have ever had pancreatitis, gallstones, a history of alcoholism, or high triglyceride levels.

Stop taking GLYXAMBI 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 to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

For more information, please see Important Safety Information on the next page, and download the [Prescribing Information](#) and [Medication Guide](#).

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- **Heart failure.** Heart failure means your heart does not pump blood well enough. Before you start taking GLYXAMBI, tell your doctor if you have ever had heart failure or have problems with your kidneys. Contact your doctor right away if you have any of the following symptoms: increasing shortness of breath or trouble breathing, especially when you lie down; swelling or fluid retention, especially in the feet, ankles or legs; an unusually fast increase in weight or unusual tiredness. These may be symptoms of heart failure.
- **Dehydration.** GLYXAMBI can cause some people to have dehydration (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, light-headed, or weak, especially when you stand up. You may be at higher risk of dehydration if you have low blood pressure, take medicines to lower your blood pressure, including water pills (diuretics), are on a low salt diet, have kidney problems, or are 65 years of age or older.
- **Vaginal yeast infection.** Women who take GLYXAMBI may get vaginal yeast infections. Talk to your doctor if you experience vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), and/or vaginal itching.
- **Yeast infection of the penis.** Men who take GLYXAMBI may get a yeast infection of the skin around the penis, especially uncircumcised males and those with chronic infections. Talk to your doctor if you experience redness, itching or swelling of the penis, rash of the penis, foul smelling discharge from the penis, and/or pain in the skin around penis.
- **Ketoacidosis (increased ketones in your blood or urine).** Ketoacidosis is a serious condition, which may need to be treated in the hospital. Ketoacidosis may lead to death. Ketoacidosis occurs in people with type 1 diabetes and can also occur in people with type 2 diabetes taking GLYXAMBI, even if blood sugar is less than 250 mg/dL. **Stop taking GLYXAMBI and call your doctor right away if you get any of the following symptoms** and, if possible, check for ketones in your urine:
 - nausea
 - vomiting
 - stomach-area (abdominal) pain
 - tiredness
 - trouble breathing
- **Kidney problems.** Sudden kidney injury has happened to people taking GLYXAMBI. Talk to your doctor right away if you reduce the amount you eat or drink, or if you lose liquids; for example, from vomiting, diarrhea, or being in the sun too long.
- **Serious urinary tract infections.** Serious urinary tract infections can occur in people taking GLYXAMBI and may lead to hospitalization. Tell your doctor if you have symptoms of a urinary tract infection, such as a burning feeling when passing urine, a need to urinate often or right away, pain in the lower part of your stomach or pelvis, or blood in the urine. Sometimes people also may have a fever, back pain, nausea, or vomiting.
- **Low blood sugar (hypoglycemia)**, if you take GLYXAMBI 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 or insulin may need to be lowered. Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, confusion, irritability, hunger, fast heartbeat, sweating, dizziness, or shaking or feeling jittery.

- **Necrotizing fasciitis.** A rare but serious bacterial infection that causes damage to the tissue under the skin in the area between and around your anus and genitals (perineum). This bacterial infection has happened in women and men who take GLYXAMBI, and may lead to hospitalization, multiple surgeries, and death. **Seek medical attention immediately if you have fever or are feeling very weak, tired or uncomfortable (malaise), and you develop any of the following symptoms in the area between and around your anus and genitals: pain or tenderness, swelling, and redness of skin (erythema).**

- **Allergic (hypersensitivity) reactions.** Symptoms of a serious allergic reaction to GLYXAMBI may include swelling of your face, lips, throat, and other areas on your skin; difficulty with swallowing or breathing; raised, red areas on your skin (hives); skin rash, itching, flaking, or peeling. If you have any of these symptoms, stop taking GLYXAMBI and call your doctor or go to the emergency room right away.

- **Increased fats in your blood (cholesterol)**

- **Joint pain.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in GLYXAMBI, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.

- **Skin reaction** called bullous pemphigoid can be serious and may need to be treated in a hospital. Tell your doctor right away if you develop blisters.

The most common side effects of GLYXAMBI include urinary tract infections, stuffy or runny nose and sore throat, and upper respiratory tract infections.

These are not all the possible side effects of GLYXAMBI. For more information, ask your doctor or pharmacist.

Before taking GLYXAMBI, tell your doctor if you have kidney problems. Your doctor may do blood tests to check your kidneys before and during your treatment with GLYXAMBI. Also tell your doctor if you have liver problems, have a history of infection of the vagina or penis, have a history of urinary tract infections or problems with urination, are going to have surgery, are eating less due to illness, surgery, or a change in your diet, have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas, drink alcohol very often, or drink a lot of alcohol in the short term ("binge" drinking), have any other medical conditions, are pregnant or plan to become pregnant. GLYXAMBI may harm your unborn baby. Tell your doctor right away if you become pregnant during treatment with GLYXAMBI, are breastfeeding or are planning to breastfeed. GLYXAMBI may pass into your breast milk and may harm your baby. Do not breastfeed while taking GLYXAMBI.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. GLYXAMBI may affect the way other medicines work, and other medicines may affect how GLYXAMBI works.

Especially tell your doctor if you take:

- insulin or other medicines that can lower your blood sugar
- diuretics (water pills)
- rifampin (Rifadin®, Rimactane®, Rifater®, Rifamate®),* an antibiotic that is used to treat tuberculosis

*These trademarks are owned by third parties not affiliated with GLYXAMBI.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Glyxambi[®]
(empagliflozin/linagliptin) tablets
10 mg/5 mg, 25 mg/5 mg