

SCHEDULING STATUS: **S4**



Glyxambi® 10/5 mg
Glyxambi® 25/5 mg
film-coated tablets
empagliflozin/linagliptin
Sugar free. Contains mannitol.

Read all of this leaflet carefully before you start taking GLYXAMBI

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- GLYXAMBI has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What GLYXAMBI is and what it is used for
2. What you need to know before you take GLYXAMBI
3. How to take GLYXAMBI
4. Possible side effects
5. How to store GLYXAMBI
6. Contents of the pack and other information

1. What GLYXAMBI is and what it is used for

GLYXAMBI is used to lower blood sugar levels in patients with type 2 diabetes mellitus.

GLYXAMBI may be used when diet plus exercise do not provide adequate blood sugar level control either alone or with certain other medicines for diabetes such as metformin.

Type 2 diabetes mellitus develops if the body does not make enough insulin or if the insulin that your body makes does not work as well as it should.

Insulin is a substance which helps to lower the level of sugar in your blood, especially after meals.

When the level of sugar builds up in your blood, this can cause damage to the body's cells and lead to serious problems with your heart, brain, eyes, circulation, nerves or kidneys.

GLYXAMBI contains two different active ingredients:

- empagliflozin, which belongs to a group of medicines called SGLT2 (sodium glucose co-transporter 2) inhibitors, and

- linagliptin, which belongs to a group of medicines called DPP-4 (dipeptidyl peptidase 4) inhibitors.

Both medicines work together to control blood sugar levels in patients with type 2 diabetes mellitus by increasing the amount of glucose expelled in urine, and producing more insulin to lower blood sugar levels.

Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness and foot amputation.

Along with diet and exercise, GLYXAMBI helps lower your blood sugar.

Continue to follow the diet and/or exercises recommended for you while you are on treatment with GLYXAMBI.

GLYXAMBI can also be used as an alternative to taking both empagliflozin (or other SGLT2 inhibitors) and linagliptin (or other DPP-4 inhibitors) as single tablets. In this case, do not continue taking any one of those tablets separately if you are taking GLYXAMBI.

2. What you need to know before you take GLYXAMBI

Do not take GLYXAMBI

- if you are hypersensitive (allergic) to empagliflozin, linagliptin or any of the other ingredients of GLYXAMBI (listed in Section 6).
- if your doctor has told you that you have severe problems with your kidneys.

Warnings and precautions

Before you start to take GLYXAMBI

- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.
- Tell your doctor if you have or have had any of the following medical conditions:
 - type 1 diabetes, a condition where your body does not produce insulin.
 - diabetic ketoacidosis, a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include: rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat.
 - kidney problems.
 - if you have or have had a disease of the pancreas.
 - illnesses that will make you dehydrated (e.g. diarrhoea or a severe infection).
 - frequent genital or urinary tract infections (infections of the bladder, kidney, or tubes that carry urine).
 - increased urine loss which may affect the fluid balance in your body.
- Tell your doctor if you have heart problems, history of low blood pressure or are 75 years of age or older.

Increased passing of urine due to GLYXAMBI may affect fluid balance in your body and increase your risk of dehydration.

You should not start taking GLYXAMBI if you are over 75 years of age.

If you have not told your doctor about any of the above, tell him/her before you start taking GLYXAMBI.

While you are taking GLYXAMBI

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking GLYXAMBI.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking GLYXAMBI.
- If you become pregnant while taking GLYXAMBI, tell your doctor immediately.
- If you are about to have any blood or urine tests, tell your doctor that you are taking GLYXAMBI. It may interfere with the results of some tests.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure GLYXAMBI is working and to prevent unwanted side effects.
- Follow your healthcare provider's advice on diet, drinking alcohol and exercise. Diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise program recommended by your healthcare provider while taking GLYXAMBI.
- Make sure you check your blood glucose regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.
- Check your feet regularly and see your doctor if you notice any problems. Follow any other advice regarding foot care given by your doctor.
- Talk to your doctor about when to stop taking GLYXAMBI and when to start taking it again if you are about to have surgery.
- Tell your healthcare provider right away if you have unexplained muscle pain, tenderness or weakness and dark or discoloured urine. Muscle problems including muscle breakdown can be serious and may cause kidney damage. The risk may be higher if you have abnormal kidney function or when taking other medicines such as 'statins' or colchicine.

Children and adolescents

Do not give GLYXAMBI to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Other medicines and GLYXAMBI

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines and GLYXAMBI may interfere with each other. These include:

- medicines used to treat high blood pressure known as 'water pills' (diuretics).
- rifampicin (an antibiotic medicine used to treat certain infections such as tuberculosis).
- carbamazepine, phenobarbital (phenobarbitone) or phenytoin (medicines used to control fits (seizures) or chronic pain).
- a medicine used to treat and prevent mood disorders (lithium).

These medicines may be affected by GLYXAMBI or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking GLYXAMBI.

GLYXAMBI with food, drink and alcohol

Follow your doctor's and/or dietician's advice on diet and exercise.

Be careful when drinking alcohol, as this may increase the risk of your blood glucose becoming too low, and alcohol abuse may predispose you to developing ketoacidosis.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking GLYXAMBI.

Do not take GLYXAMBI if you are pregnant.
It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking GLYXAMBI.
It is not known whether the active ingredients in GLYXAMBI pass into human breastmilk and there is a possibility that your baby may be affected.

Driving and using machines

Be careful driving or operating machinery until you know how GLYXAMBI affects you.

When taken with other anti-diabetic medicines, such as sulphonylurea or insulin, your risk of getting low blood sugar is higher.
This may cause dizziness, light-headedness, or weakness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery.
If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when doing any of the following things, which may increase the risk of your blood glucose becoming too low:

- drinking alcohol
- not eating enough
- doing unexpected or vigorous exercise.

3. How to take GLYXAMBI

Do not share medicines prescribed for you with any other person.

Always take GLYXAMBI exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual starting dose is one GLYXAMBI 10/5 mg tablet once a day.

Your doctor may increase your dose to one GLYXAMBI 25/5 mg tablet once a day.

Your doctor will prescribe GLYXAMBI alone or in combination with another anti-diabetic medicine if that medicine alone is not sufficient to control your blood sugar level.

Swallow the tablet whole with a full glass of water.

Take GLYXAMBI at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take GLYXAMBI before or after food.

Your doctor will tell you how long your treatment with GLYXAMBI will last. Do not stop treatment early because your blood sugar levels may increase if you stop taking GLYXAMBI.

GLYXAMBI helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you have the impression that the effect of GLYXAMBI is too strong, or too weak, tell your doctor or pharmacist.

If you take more GLYXAMBI than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you forget to take GLYXAMBI

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you stop taking GLYXAMBI

Do not stop taking GLYXAMBI or lower the dosage without checking with your doctor.

4. Possible side effects

GLYXAMBI can have side effects.

Not all side effects reported for GLYXAMBI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GLYXAMBI, please consult your healthcare provider for advice.

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

- develop blisters or the breakdown of the outer layer of your skin (erosion). These may be signs of a skin reaction called bullous pemphigoid or another severe skin reaction. Your doctor may tell you to stop taking GLYXAMBI.
- allergic reaction (shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other part of the body, rash, itching or hives on the skin).

These are all very serious side effects that occur less frequently. If you have them, you may have had a serious reaction to GLYXAMBI. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- rapid weight loss, feeling sick or being sick, stomach pain, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat. In rare cases, empagliflozin, one of the active substances in GLYXAMBI can cause a serious side effect called diabetic ketoacidosis.
- severe upper stomach pain, radiating to the back, nausea, vomiting and fever (which may be symptoms of an inflamed pancreas – pancreatitis).
- experience muscle pain, tenderness or weakness with dark or discoloured urine which may be symptoms of rhabdomyolysis.
- experience pain or tenderness, itching, swelling in the genital or back passage area, fever or are generally feeling unwell. These may be symptoms of a serious and life-threatening infection called Fournier's gangrene. Your doctor may tell you to stop taking GLYXAMBI.
- experience swelling of the penis that makes it difficult to pull back the skin around the tip of the penis (uncircumcised men).

These are all serious side effects whose frequency is unknown. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice the following:

- any of the symptoms of low blood sugar such as sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, a fast pounding heartbeat.

Low blood sugar may frequently occur in people who already take another medication to treat diabetes, such as a sulphonylurea or insulin. The dose of your sulphonylurea or insulin medicine may need to be reduced while taking GLYXAMBI.

Frequent:

- burning sensation when passing urine
- urine that appears cloudy
- pain in the pelvis, or mid-back pain
- straining or pain when passing urine
- swelling of the nose or throat (nasopharyngitis)
- cough
- painful, swollen joints
- genital burning, redness, pain and discharge which may be signs of a genital yeast infection
- itching
- passing more urine than normal

- constipation
- increased blood fats (lipids)
- increased blood enzyme amylase
- increased pancreas enzyme lipase.

Less frequent:

- signs of dehydration including unusual thirst, light-headedness or dizziness upon standing, fainting or loss of consciousness
- mouth ulceration.

Laboratory blood tests may show an increase in the amount of red blood cells (increase in haematocrit), and changes related to kidney function (decrease in filtration rate and increase in blood creatinine).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of GLYXAMBI.

Suspected adverse reactions can also be reported directly to the holder of the certificate of registration using the email address
pv_local_south_africa@boehringer-ingelheim.com.

5. How to store GLYXAMBI

Store at or below 30 °C.

Store all medicines out of reach of children.

Keep your tablets in the pack until it is time to take them. If you store the tablets out of the pack they may not keep well.

Do not store GLYXAMBI in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Do not take GLYXAMBI after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What GLYXAMBI contains

The active substances are empagliflozin and linagliptin.

- Each GLYXAMBI 10/5 mg film-coated tablet contains 10 mg empagliflozin and 5 mg linagliptin.
- Each GLYXAMBI 25/5 mg film-coated tablet contains 25 mg empagliflozin and 5 mg linagliptin.

The other ingredients are:

- mannitol (GLYXAMBI 10/5 mg: 107 mg/tablet, GLYXAMBI 25/5 mg: 92 mg/tablet)
- pregelatinised maize starch
- maize starch
- copovidone
- crospovidone
- purified talc
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol
- iron oxide yellow (GLYXAMBI 10/5 mg)
- iron oxide red (GLYXAMBI 25/5 mg)

GLYXAMBI does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What GLYXAMBI looks like and contents of the pack

- GLYXAMBI 10/5 mg tablets are pale yellow, arc triangular, flat-faced, bevel-edged, film-coated tablets. One side is debossed with the Boehringer Ingelheim company symbol, the other side is debossed with '10/5'.
- GLYXAMBI 25/5 mg tablets are pale pink, arc triangular, flat-faced, bevel-edged, film-coated tablets. One side is debossed with the Boehringer Ingelheim company symbol, the other side is debossed with '25/5'.

GLYXAMBI is available in transparent PVC/PVDC/Aluminium blister packs containing 30 film-coated tablets.

Holder of Certificate of Registration

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