

Glyxambi[®] Film-Coated Tablets

Empagliflozin/ linagliptin (10mg/5mg and 25mg/5mg)

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1. What *GLYXAMBI* is used for

Glyxambi is used to lower blood sugar level in diabetes patients.

Glyxambi can be used when diet, exercise and treatment with one of the mono-component of *Glyxambi* with/without metformin do not provide adequate glycaemic control.

Glyxambi can also be used as a replacement to taking both empagliflozin and linagliptin as single tablets. In this case, do not continue taking any one of those tablets separately if you are taking this medicine.

It is important that you continue with your diet and exercise plan as recommended by your doctor, pharmacist or nurse.

2. How *GLYXAMBI* works

Glyxambi is an anti-diabetic medicine that contains two active substances called empagliflozin and linagliptin:

- Empagliflozin works by blocking a protein in the kidneys called sodium glucose co-transporter 2 (SGLT2). SGLT2 prevents glucose from being excreted in urine by absorbing glucose back into the bloodstream as blood is being filtered in the kidneys. By blocking this protein, the medicine causes glucose (blood sugar), sodium (salt) and water to be removed via the urine. This helps to lower blood glucose levels, which are too high because of your type 2 diabetes.

- Linagliptin works in a different way, namely by enabling the pancreas to produce more insulin to lower blood glucose levels. It does this by blocking a protein called DPP-4.

3. Before you use *GLYXAMBI*

- When you must not use it

Do not take *Glyxambi* if you are allergic to empagliflozin, linagliptin, any other SGLT2 inhibitor (e.g. dapagliflozin, canagliflozin), any other DPP-4 inhibitor (e.g. sitagliptin, vildagliptin), or any of the ingredients of this medicine (listed in section 8)

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is not known whether *Glyxambi* is harmful to the unborn child. As a precautionary measure it is preferable to avoid the use of this medicine during pregnancy.

It is not known whether the active substances of *Glyxambi* pass into human breast milk. Do not use this medicine if you are breast-feeding.

It is not known whether *Glyxambi* has an effect on the fertility in humans.

- Before you start to use it

Talk to your doctor, before taking this medicine, and during treatment:

- Ask about ways to prevent dehydration.
- If you have “type 1 diabetes”. This type usually starts when you are young and your body does not produce any insulin. You should not take *Glyxambi* if you have type 1 diabetes.
- If you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, 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.

Contact a doctor or the nearest hospital straight away as these symptoms could be a sign of “diabetic ketoacidosis” – a rare, but serious, sometimes life-threatening problem you can get with diabetes because of increased levels of ketone bodies in your urine or blood, seen in tests. The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration or sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.

- If you taking other anti-diabetic medicines known as sulphonylureas (e.g. gliclazide, glipizide) and/or insulin. Your doctor may want to reduce your dose of these medicines when you take them together with *Glyxambi*, in order to avoid too low blood sugar (hypoglycaemia).
- If you have or have had a disease of the pancreas.
- If you have serious kidney problems. Your doctor may ask you to take a different medicine.
- If you are 75 years old or older, as increased passing of urine due to the medicine may affect fluid balance in your body and increase your risk of dehydration. For possible signs of dehydration, see section 6.

Contact your doctor if you experience any of the following during treatment with *Glyxambi*:

- If you develop symptoms of acute pancreatitis, like persistent, severe abdominal pain. Possible signs are listed in section 6, ‘Side effects’. Your doctor may need to change your treatment.
- If you are being sick, have diarrhoea or fever, or if you are not able to eat or drink. These conditions can cause dehydration. Your doctor may ask you to stop taking *Glyxambi* until you recover, to prevent loss of too much body fluid.
- If you have a serious infection of the kidney or the urinary tract with

fever. Your doctor may ask you to stop taking *Glyxambi* until you have recovered.

- If you encounter blistering of the skin. It may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop *Glyxambi*.

Talk to your doctor immediately if you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier's gangrene which destroys the tissue under the skin. Fournier's gangrene has to be treated immediately.

- Taking other medicines

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, you should tell your doctor if you are using the following medicines:

- other anti-diabetic medicines, such as insulin or a sulphonylurea. Your doctor may want to lower the dose of these other medicines, to prevent your blood sugar levels from getting too low.
- medicines used to remove water from your body (diuretics). Your doctor may ask you to stop taking *Glyxambi*.
- medicines that might have an effect on the breakdown of empagliflozin or linagliptin in your body such as rifampicin (an antibiotic used to treat tuberculosis) or certain medicines used to treat seizures (such as carbamazepine, phenobarbital or phenytoin). The effect of *Glyxambi* may be reduced.
- lithium because *Glyxambi* can lower the amount of lithium in your blood.

4. How to use GLYXAMBI

- How much to use

The usual starting dose is 10 mg empagliflozin plus 5 mg linagliptin once a day. For this dose *Glyxambi* is available as 10 mg/5 mg film coated tablets.

Your doctor will decide whether you need to increase your dose to one film-coated tablet of *Glyxambi* 25 mg/5 mg (25 mg empagliflozin plus 5 mg linagliptin) once a day. If you already take 25 mg empagliflozin and 5 mg linagliptin as separate tablets and you switch to *Glyxambi*, you can start directly with *Glyxambi* 25 mg/5 mg.

Renal impairment:

Talk to your doctor if you have kidney problems. Your doctor may limit your dose or decide to use an alternative medicine.

Hepatic impairment:

Talk to your doctor in case you suffer from severe hepatic impairment. *Glyxambi* is not recommended and your doctor may decide to use an alternative medicine.

Children and adolescents:

This medicine is not recommended for children and adolescents under 18 years, because it has not been studied in these patients.

Taking this medicine

- Swallow the tablet whole with water.
- You can take *Glyxambi* with or without food.
- You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

Your doctor may prescribe *Glyxambi* together with another anti-diabetic medicine. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

Diet and exercise can help your body to use its blood sugar better. It is important to stay on the diet and exercise program recommended by your doctor during treatment with this medicine.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Glyxambi* for as long as your doctor recommends.

Do not stop taking this medicine without first consulting your doctor. Your blood sugar levels may increase when you stop taking *Glyxambi*.

- If you forget to use it

- 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 of this medicine to make up for a forgotten dose.

- If you use too much (overdose)

If you take more of this medicine than you should, immediately talk to a doctor or go to a hospital. Take the medicine pack with you.

5. While you are using it

- Things you must do

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

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.

- Things you must not do

Do not stop taking this medicine without first consulting your doctor. Your blood sugar levels may increase when you stop taking *Glyxambi*.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

- Things to be careful of
Foot care

Like for all diabetic patients it is important to check your feet regularly and adhere to any other advice regarding

foot care given by your health care professional.

Kidney function

Before you start treatment with *Glyxambi* and regularly during treatment, your doctor will check how well your kidneys are working.

Urine glucose

Because of how this medicine works, your urine will test positive for sugar while you are taking this medicine.

Driving and using machines

Glyxambi has minor influence on the ability to drive and use machines.

Taking *Glyxambi* in combination with sulphonylureas or insulin can cause your blood sugar levels to drop too low (hypoglycaemia), which may cause symptoms such as shaking, sweating and changes in vision, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you experience any of these symptoms while taking *Glyxambi*.

6. Side Effects

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

Contact a doctor or the nearest hospital straight away if you have any of the following side effects:

Diabetic ketoacidosis, seen rarely (may affect up to 1 in 1,000 people)

These are the signs of diabetic ketoacidosis (see also section 3):

- increased levels of “ketone bodies” in your urine or blood
- rapid weight loss
- feeling sick or being sick
- stomach pain
- excessive thirst
- 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

This may occur regardless of blood glucose level. Your doctor may decide to

temporarily or permanently stop your treatment with this medicine.

Contact your doctor immediately if you notice any of the following side effects:

Allergic reactions, seen uncommonly (may affect up to 1 in 100 people)

This medicine may cause allergic reactions, which may be serious, including hives (urticaria) and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing (angioedema).

Inflammation of the pancreas (pancreatitis), seen uncommonly

This medicine may cause pancreatitis, which usually shows as persistent, severe abdominal (stomach) pain that might reach through to your back, often accompanied by feeling sick or being sick. Your doctor will need to change your treatment.

Low blood sugar (hypoglycaemia), seen commonly (may affect up to 1 in 10 people)

If you take *Glyxambi* with another medicine that can cause low blood sugar, such as a sulphonylurea or insulin, you are at risk of getting too low blood sugar (hypoglycaemia). The signs of too low blood sugar may include:

- shaking, sweating, feeling very anxious or confused, fast heart beat
- excessive hunger, headache

Your doctor will tell you how to treat low blood sugar levels and what to do if you get any of the signs above. If you have symptoms of low blood sugar, eat glucose tablets, a high sugar snack or drink fruit juice. Measure your blood sugar if possible and rest.

Urinary tract infection, seen commonly

The signs of urinary tract infection are:

- burning sensation when passing urine
- urine that appears cloudy
- pain in the pelvis, or mid-back pain (when kidneys are infected)

An urge to pass urine or more frequent urination may be due to the way this medicine works, but as they can also be

signs of urinary tract infection, if you note an increase in such symptoms, you should also contact your doctor.

Loss of body fluid (dehydration), seen uncommonly

The signs of dehydration are not specific, but may include:

- Unusual thirst
- Lightheadedness or dizziness upon standing
- Fainting or loss of consciousness

Other side effects while taking

Glyxambi:

Seen commonly

- genital yeast infection like thrush
- inflamed nose or throat (nasopharyngitis)
- cough
- passing more urine than usual or needing to pass urine more often
- itching
- skin rash
- increased blood enzyme amylase
- increased pancreas enzyme lipase
- thirst
- constipation

Seen uncommonly

- straining or pain when emptying the bladder
- laboratory blood tests may show changes in blood fat levels, 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)

Seen rarely

- sore in the mouth

Frequency not known (cannot be estimated from the available data)

- blistering of skin (bullous pemphigoid)
- necrotizing fasciitis of the perineum or Fournier’s gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus

Reporting of Suspected side effects

You may report any side effects or adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of GLYXAMBI

- Storage

Keep this medicine out of the reach and sight of children.
Store below 30°C.

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the packaging is damaged or shows signs of tampering.

- Disposal

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

8. Product Description

- What it looks like

Glyxambi 10mg/5mg: 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 25mg/5mg: 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".

- Ingredients

Active ingredient:
Empagliflozin and linagliptin

Inactive ingredients:

Tablet core

Mannitol, Pregelatinized starch, Maize starch, Copovidone, Crospovidone, Talc, Magnesium stearate

Film coating

Hypromellose 2910, Mannitol, Talc, Titanium dioxide, Macrogol 6000, Iron oxide yellow (for 10mg/5mg Tablets) and Iron oxide red (for 25mg/5mg Tablets).

- MAL numbers:

Glyxambi Film-Coated Tablets
10mg/5mg: MAL18016005AZ
Glyxambi Film-Coated Tablets
25mg/5mg: MAL18016004AZ

9. Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG
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10. Product Registration Holder

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11. Date of revision

15/04/2025

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