

Package leaflet: Information for the patient

Glyxambi® 10 mg/5 mg film-coated tablets

Glyxambi® 25 mg/5 mg film-coated tablets

empagliflozin/linagliptin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What Glyxambi is

Glyxambi contains two active substances called empagliflozin and linagliptin. Each belongs to a group of medicines called “oral anti-diabetics”. These are medicines taken by mouth to treat type 2 diabetes.

What is type 2 diabetes?

Type 2 diabetes is a condition that comes from both your genes and your lifestyle. If you have type 2 diabetes, your pancreas may not make enough insulin to control the level of glucose in your blood, and your body is unable to use its own insulin effectively. This results in high levels of sugar in your blood, which can lead to medical problems like heart disease, kidney disease, blindness, and poor circulation in your limbs.

How Glyxambi works

Empagliflozin belongs to a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors. It works by blocking the SGLT2 protein in your kidneys. This causes blood sugar (glucose) to be removed in your urine. 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.

Thereby Glyxambi lowers the amount of sugar in your blood.

What Glyxambi is used for

- Glyxambi is added to metformin and/or sulphonylurea (SU) to treat type 2 diabetes in adult patients aged 18 years and older whose diabetes cannot be controlled when treated with metformin and/or sulphonylurea in combination with empagliflozin, or when treated with metformin and/or sulphonylurea in combination with linagliptin.
- Glyxambi can also be used as an alternative to taking both empagliflozin and linagliptin as single tablets. To avoid overdose, do not continue taking empagliflozin and linagliptin 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. What you need to know before you take Glyxambi

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 other ingredients of this medicine (listed in section 6).

Warnings and precautions

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

- 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 and stop taking this medicine until further advice from your doctor. 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 are taking other anti-diabetic medicines known as “sulphonylurea” (e.g. glimepiride, glipizide) and/or using 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 limit your daily dose or ask you to take a different medicine (see also section 3, ‘How to take Glyxambi’).
- if you have serious liver problems. Your doctor may ask you to take a different medicine.

- if you might be at risk of dehydration, for example:
 - o if you are being sick, have diarrhoea or fever, or if you are not able to eat or drink
 - o if you are taking medicines that increase urine production [diuretics] or lower blood pressure
 - o if you are over 75 years old
- Possible signs are listed in section 4 under ‘dehydration’. Your doctor may ask you to stop taking Glyxambi until you recover to prevent loss of too much body fluid. Ask about ways to prevent dehydration.
- if you have an increase in the proportion of red blood cells in your blood (haematocrit), seen in laboratory blood tests (see also section 4, ‘Possible side effects’).

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

- if you develop symptoms of acute pancreatitis, like persistent, severe stomach ache (abdominal pain). Possible signs are listed in section 4, ‘Possible side effects’. Your doctor may need to change your treatment.
- 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.

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.

Children and adolescents

This medicine is not recommended for children and adolescents under 18 years as linagliptin is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

Other medicines and Glyxambi

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 break down 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.

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.

Driving and using machines

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

Taking this medicine 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.

3. How to take Glyxambi

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

How much to take

The usual starting dose is one film-coated tablet of Glyxambi 10 mg/5 mg (10 mg empagliflozin and 5 mg linagliptin) once a day.

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 and 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.

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.

Appropriate diet and exercise help your body to use its blood sugar better. It is important to stay on the diet and exercise program recommended by your doctor while taking Glyxambi.

If you take more Glyxambi than you should

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.

If you forget to take Glyxambi

What to do if you forget to take a tablet depends on how long it is until your next 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 of this medicine to make up for a forgotten dose.

If you stop taking Glyxambi

Do not stop taking this medicine without first consulting your doctor, unless you suspect you have diabetic ketoacidosis (see section 2 “warnings and precautions”). 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.

4. Possible side effects

Like all medicines, this medicine 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 2, 'Warnings and precautions'):

- 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
- necrotising 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

Seen very rarely

- inflammation of the kidneys (tubulointerstitial nephritis)

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

- blistering of skin (bullous pemphigoid)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Glyxambi

Store below 30°C

Keep this medicine out of the sight and reach of children.

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.

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

6. Contents of the pack and other information

What Glyxambi contains

Glyxambi 10 mg/5 mg film-coated tablets

- The active substances are empagliflozin and linagliptin. Each film-coated tablet contains 10 mg empagliflozin and 5 mg linagliptin.

- The other ingredients are:

Tablet core: mannitol (E421), pre-gelatinised starch (maize), maize starch, copovidone, crospovidone, talc and magnesium stearate.

Film coating: hypromellose, mannitol (E421), talc, titanium dioxide (E171), macrogol 6000 and iron oxide yellow (E172).

Glyxambi 25 mg/5 mg film-coated tablets

- The active substances are empagliflozin and linagliptin. Each film-coated tablet contains 25 mg empagliflozin and 5 mg linagliptin.

- The other ingredients are:

Tablet core: mannitol (E421), pre-gelatinised starch (maize), maize starch, copovidone, crospovidone, talc and magnesium stearate.

Film coating: hypromellose, mannitol (E421), talc, titanium dioxide (E171), macrogol 6000 and iron oxide red (E172).

What Glyxambi looks like and contents of the pack

Glyxambi 10 mg/5 mg film-coated tablets (tablets) are pale yellow, arc triangular, flat faced and bevel-edged. They have “10/5” on one side and the Boehringer Ingelheim logo on the other side. Each side of the tablet is 8 mm long.

Glyxambi 25 mg/5 mg film-coated tablets (tablets) are pale pink, arc triangular, flat faced and bevel-edged. They have “25/5” on one side and the Boehringer Ingelheim logo on the other side. Each side of the tablet is 8 mm long.

Glyxambi is available in PVC/PVDC/aluminium perforated unit dose blisters.

The pack sizes are 7 (7's blister x 1), 10 (10's blister x 1), 14 (7's blister x 2), 28 (7's blister x 4), 30 (10's blister x 3), 60 (10's blister x 6), 70 (7's blister x 10), 90 (10's blister x 9), and 100 film-coated tablets.

Not all strengths and pack sizes are registered or marketed in your country.

Marketing Authorisation Holder

Boehringer Ingelheim International GmbH
Binger Str. 173
D-55216 Ingelheim am Rhein
Germany

Manufacturer & Batch release site

Rottendorf Pharma GmbH
Ostenfelder Straße 51- 61
59320 Ennigerloh
Germany

Primary and secondary packaging site

Rottendorf Pharma GmbH
Am Fleigendahl 3, 59320 Ennigerloh,
Germany

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Boehringer Ingelheim
Middle East & North Africa (Scientific Office)
Dubai, UAE.
Tel: +971 (4) 423 0400
Fax: +971 (4) 423 3637

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists