

Glyxambi®

10 mg/5 mg and 25 mg/5 mg

empagliflozin and linagliptin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Glyxambi. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Glyxambi against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au (Australia) and www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp (New Zealand) and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with the medicine.

You may need to read it again.

What Glyxambi 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 is also called non-insulin-dependent diabetes mellitus or NIDDM.

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.

How Glyxambi works

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, this medicine 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 this medicine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription. It is not addictive.

Before you take Glyxambi

When you must not take it

Do not take Glyxambi if you have an allergy to:

- any medicine containing empagliflozin or linagliptin (the active ingredients in Glyxambi)
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Glyxambi if you have severe problems with your kidneys.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

It is not known whether the active ingredients in Glyxambi pass into human breast milk and there is a possibility that your baby may be affected.

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

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

Do not take this medicine 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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 included: 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).

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 the medicine may affect fluid balance in your body and increase your risk of dehydration.

Tell your doctor if you are 75 years of age or older.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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 or phenytoin (medicines used to control fits (seizures) or chronic pain).

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 this medicine.

How to take Glyxambi

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The recommended starting dose is one Glyxambi 10 mg/5 mg tablet once a day.

Your doctor may increase your dose to one Glyxambi 25 mg/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.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take your medicine 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 this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine 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 forget to take it

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia telephone 13 11 26; in New Zealand telephone 0800 764 766) for advice, or go to Emergency if you think that you or anyone else may have taken too much Glyxambi. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Glyxambi

Things you must do

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 this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

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 the medicine is working and to prevent unwanted side effects.

Follow your doctor's and/or dietician'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 doctor 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.

Things you must not do

Do not take Glyxambi to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

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

When taken with other anti-diabetic medicines, such as sulfonylurea 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Glyxambi.

This medicine helps most people with type 2 diabetes mellitus, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- swelling of the nose or throat (nasopharyngitis)
- mouth ulceration
- cough
- signs of dehydration including unusual thirst, light-headedness or dizziness upon standing, fainting or loss of consciousness
- genital burning, redness, pain and discharge which may be signs of a genital yeast infection
- itching
- passing more urine than normal.

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

- burning sensation when passing urine
- urine that appears cloudy
- pain in the pelvis, or mid-back pain
- straining or pain when passing urine
- unusual thirst
- light-headedness, or dizziness upon standing
- fainting or loss of consciousness.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor as soon as possible if you notice 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 occur in patients who already take another medication to treat diabetes, such as a sulfonylurea or insulin. The dose of your sulfonylurea or insulin medicine may need to be reduced while taking Glyxambi.

Tell your doctor immediately if you develop blisters or the breakdown of the outer layer of your skin (erosion).

These may be signs of a skin reaction called bullous pemphigoid. Your doctor may tell you to stop taking Glyxambi.

Tell your doctor immediately if you 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.

Tell your doctor immediately or go to Emergency if you notice any of the following:

- 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)
- severe upper stomach pain, radiating to the back, nausea, vomiting and fever (which may be symptoms of an inflamed pancreas – pancreatitis)
- 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 (diabetic ketoacidosis).

In rare cases, empagliflozin, one of the active substances in Glyxambi can cause a serious side effect called diabetic ketoacidosis.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After taking Glyxambi

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Glyxambi or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

- Glyxambi 10 mg/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 mg/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 blister packs containing 10 (sample) and 30 tablets.

Ingredients

Active ingredients:

Each Glyxambi 10 mg/5 mg tablet contains 10 mg empagliflozin and 5 mg linagliptin.

Each Glyxambi 25 mg/5 mg tablet contains 25 mg empagliflozin and 5 mg linagliptin.

Inactive ingredients:

- mannitol
- pregelatinised maize starch
- maize starch
- copovidone
- crospovidone
- purified talc
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 6000
- iron oxide yellow (Glyxambi 10 mg/5 mg)
- iron oxide red (Glyxambi 25 mg/5 mg).

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

Supplier

Glyxambi is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney NSW

www.boehringer-ingelheim.com.au

They are supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited

Auckland

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Australian Registration Numbers

Glyxambi 10 mg/5 mg

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