

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****EMPAGLIFLOZIN 10 ZYDUS film-coated tablets****EMPAGLIFLOZIN 25 ZYDUS film-coated tablets****Empagliflozin****Contains sugar (lactose):****Each EMPAGLIFLOZIN 10 ZYDUS film-coated tablet contains 22,4 mg lactose.****Each EMPAGLIFLOZIN 25 ZYDUS film-coated tablet contains 56,0 mg lactose.****Read all of this leaflet carefully before you start taking EMPAGLIFLOZIN ZYDUS.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.
- EMPAGLIFLOZIN ZYDUS 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.

EMPAGLIFLOZIN ZYDUS is used together with diet and exercise to lower blood sugar in adults with type 2 diabetes only.

Do not take EMPAGLIFLOZIN ZYDUS if you have type 1 diabetes.

EMPAGLIFLOZIN ZYDUS is not used to control body weight.

There have been reports of metabolic acidosis or ketoacidosis in people taking EMPAGLIFLOZIN ZYDUS which is life-threatening and needs to be treated in hospital.

If you have any symptoms of metabolic acidosis such as 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, you must immediately contact a doctor or the nearest hospital in order to be assessed for metabolic acidosis, even if your blood glucose level is below 11 mmol/L.

Please refer to “Take special care with EMPAGLIFLOZIN ZYDUS”.

What is in this leaflet

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

1. What EMPAGLIFLOZIN ZYDUS is and what it is used for

- EMPAGLIFLOZIN ZYDUS is used to treat type 2 diabetes in adult patients to improve blood sugar (glucose) control together with diet and exercise.
- EMPAGLIFLOZIN ZYDUS can also be used with other medicines for the treatment of diabetes. These may be medicines taken by mouth or given by injection, such as insulin.
- EMPAGLIFLOZIN ZYDUS is also used in adults with type 2 diabetes if you have an increased cardiovascular risk (health problems due to your heart and blood vessels), to lower the risk of dying from a heart attack or other events related to your heart or blood vessels, or to reduce the risk of being admitted to hospital for heart failure.

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

2. What you need to know before you take EMPAGLIFLOZIN ZYDUS

Do not take EMPAGLIFLOZIN ZYDUS:

- if you are allergic to empagliflozin or any of the other ingredients of EMPAGLIFLOZIN ZYDUS (listed in section 6)
- if you have type I diabetes (high sugar levels in your blood)
- If you have increased levels of ketone bodies in your urine or blood (see **Take special care with EMPAGLIFLOZIN ZYDUS**)
- if you have severe kidney problems, or have kidney failure and are on kidney dialysis
- if you are pregnant or are breastfeeding your baby.

Warnings and precautions

Take special care with EMPAGLIFLOZIN ZYDUS

Talk to your doctor, pharmacist or nurse before taking EMPAGLIFLOZIN ZYDUS, and during treatment with EMPAGLIFLOZIN ZYDUS 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 your doctor or the nearest hospital immediately. 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, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness, or if you have or have had problems with your pancreas including pancreatitis or surgery on your pancreas.

Ketoacidosis is a serious problem which is life-threatening and needs to be treated in a hospital. It has been reported in people taking EMPAGLIFLOZIN ZYDUS, regardless of blood sugar level. Stop taking EMPAGLIFLOZIN ZYDUS and contact your doctor or the nearest hospital immediately.

- are taking or using any other medicines to lower your blood sugar, including other diabetic medicine known as a sulphonylurea, or if you are injecting insulin. Your doctor may want to reduce the dose of the sulphonylurea or insulin when you take it in combination with EMPAGLIFLOZIN ZYDUS in order to avoid low blood sugar (hypoglycaemia). Please refer to possible signs of low blood sugar listed in section 4.
- have serious kidney problems – your doctor may prescribe you a different medicine. Your kidney function should be assessed before you start taking EMPAGLIFLOZIN ZYDUS, at least 6 monthly during treatment, and if you are taking EMPAGLIFLOZIN ZYDUS together with metformin (another medicine used to control your blood sugar).
- have liver problems.
- are 75 years old or older, or have problems with low blood pressure or if you are taking medicine to treat high blood pressure and/or diuretics (medicine used to remove water from the body also known as “water tablets”) as increased passing of urine due to the medicine may affect the fluid balance in your body and increase your risk of dehydration.
- are sick or if you have diarrhoea or fever or if you are not able to eat or drink. These can cause dehydration (excessive loss of body fluid). To prevent the excessive loss of body fluid, your doctor may ask you to stop taking EMPAGLIFLOZIN ZYDUS until you have recovered.
- are 85 years old or older as you should not start taking EMPAGLIFLOZIN ZYDUS
- have a history of urinary tract infections or have a serious infection of the kidneys or urine. Your doctor may ask you to stop taking EMPAGLIFLOZIN ZYDUS until you have recovered.

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 provider.

Urine glucose

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

Children and adolescents

EMPAGLIFLOZIN ZYDUS is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

Other medicines and EMPAGLIFLOZIN ZYDUS

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines).

The following medicine may cause an interaction when taking in combination with EMPAGLIFLOZIN ZYDUS:

- medicines used to remove water from your body (diuretics, also called “water tablets”). Your doctor may ask you to stop taking EMPAGLIFLOZIN ZYDUS. Possible signs of losing too much fluid from your body are listed in section 4.
- medicines that lower the amount of sugar in your blood such as insulin or a sulphonylurea medicine. Your doctor may want to lower the dose of these other medicines to prevent your blood sugar levels from getting too low (hypoglycaemia).

EMPAGLIFLOZIN ZYDUS with food and drink

You can take EMPAGLIFLOZIN ZYDUS with or without food.

Pregnancy and breastfeeding

Do not take EMPAGLIFLOZIN ZYDUS if you are pregnant or 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 health care provider for advice before taking EMPAGLIFLOZIN ZYDUS.

It is not known if empagliflozin passes into human breast milk.

Driving and using machines

EMPAGLIFLOZIN ZYDUS has minor influence on the ability to drive a vehicle and use machines.

Taking EMPAGLIFLOZIN ZYDUS in combination with medicines called sulphonylureas or with insulin can cause blood sugar levels to drop too low (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines. Do not perform any tasks requiring your attention if you feel dizzy while taking EMPAGLIFLOZIN ZYDUS.

EMPAGLIFLOZIN ZYDUS contains lactose

EMPAGLIFLOZIN ZYDUS contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking EMPAGLIFLOZIN ZYDUS.

3. How to take EMPAGLIFLOZIN ZYDUS

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

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

- The usual dose of EMPAGLIFLOZIN ZYDUS is one 10 mg film-coated tablet once a day. Your doctor will decide whether to increase your dose to 25 mg once a day.
- Your doctor will prescribe the strength that is right for you. Do not change your dose unless your doctor has told you to.

If you take more EMPAGLIFLOZIN ZYDUS than you should

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

If you forget to take EMPAGLIFLOZIN ZYDUS

If you forget to take a dose of EMPAGLIFLOZIN ZYDUS, take it as soon as you remember it.

However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

If you stop taking EMPAGLIFLOZIN ZYDUS

Do not stop taking EMPAGLIFLOZIN ZYDUS without first consulting your doctor.

Your blood sugar levels may increase when you stop taking EMPAGLIFLOZIN ZYDUS. If you have any further questions on the use of EMPAGLIFLOZIN ZYDUS, ask your doctor, pharmacist or nurse.

4. Possible side effects

EMPAGLIFLOZIN ZYDUS can have side effects.

Not all side effects reported for EMPAGLIFLOZIN ZYDUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EMPAGLIFLOZIN ZYDUS, please consult your doctor, pharmacist or other health care provider for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EMPAGLIFLOZIN ZYDUS. 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:

- 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequently occurring:

- genital yeast infection (thrush)
- low blood sugar (hypoglycaemia) with the following symptoms:
 - shaking, sweating, feeling very anxious or confused, fast heartbeat
 - excessive hunger, headache
- urinary tract infection with the following symptoms:
 - burning sensation when passing urine
 - urine that appears cloudy
 - pain in the pelvis, or mid-back pain (when kidneys are infected)
- sugar (glucose) in the urine

- an urge to pass urine or more frequent urination may be due to the way EMPAGLIFLOZIN ZYDUS works, but they can also be signs of urinary tract infection. If you note an increase in such symptoms, you should contact your doctor
- thirst
- increased blood fats (lipids)
- blood tests may show an increase in cholesterol levels in your blood.

Less frequently occurring:

- dehydration, including the following signs:
 - unusual thirst
 - light-headedness or dizziness upon standing (low blood pressure)
 - fainting or loss of consciousness
- hives
- straining or pain when emptying the bladder
- 'ketones' in the urine
- blood tests may show a decrease in kidney function (creatinine or urea)
- blood tests may show increases in the amount of red blood cells in your blood (haematocrit).

Frequency unknown:

- 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.

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 via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's

publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of EMPAGLIFLOZIN ZYDUS.

5. How to store EMPAGLIFLOZIN ZYDUS

- Store at or below 25 °C. Protect from moisture.
- Keep blister strip in outer carton until required for use.
- Keep bottle tightly closed.
- STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What EMPAGLIFLOZIN ZYDUS contains:

The active substance is empagliflozin.

Other ingredients are copovidone, lactose anhydrous, microcrystalline cellulose, crospovidone, colloidal silicon dioxide, magnesium stearate, Opadry White (containing hypromellose, titanium dioxide, macrogol and talc).

What EMPAGLIFLOZIN ZYDUS looks like and contents of the pack:

EMPAGLIFLOZIN 10 ZYDUS: White to off-white, round, film-coated tablets debossed with “1453” on one side and plain on the other side.

EMPAGLIFLOZIN 25 ZYDUS: White to off-white, oval, film-coated tablets debossed with “1454” on one side and plain on the other side.

- Silver aluminium/aluminium blister strip packed in an outer carton.
Pack size: 10 tablets.
- White, heavyweight, 60 mL, high-density polyethylene (HDPE) bottle with blue 1 g silica gel sachet and with 33 mm child-resistant closure.
Pack sizes: 30 and 90 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Zydus Healthcare SA (Pty) Ltd

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22 Karee Street

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Not applicable.

Registration numbers

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