PATIENT INFORMATION LEAFLET

EMPAGLIFLOZIN PD RANGE

SCHEDULING STATUS:

S4

EMPAGLIFLOZIN 10 mg PD film coated tablets

EMPAGLIFLOZIN 25 mg PD film coated tablets

Empagliflozin

EMPAGLIFLOZIN PD contains sugar (lactose monohydrate) 45,2 mg per 10 mg tablet and 113 mg per 25 mg tablet.

Essentially 'sodium free'.

Read all of this leaflet carefully before you start taking EMPAGLIFLOZIN PD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- EMPAGLIFLOZIN PD 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.

Do not take EMPAGLIFLOZIN PD if you have type 1 diabetes, EMPAGLIFLOZIN PD is used together with diet and exercise to lower blood sugar in adults with type 2 diabetes only. EMPAGLIFLOZIN PD is not used to control body weight.

There have been reports of metabolic acidosis, including ketoacidosis (a serious complication of diabetes) which were serious, life threatening or fatal, in patients taking EMPAGLIFLOZIN PD.

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 also to 'Warnings and precautions'.

PATIENT INFORMATION LEAFLET

EMPAGLIFLOZIN PD RANGE

What is in this leaflet

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

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

EMPAGLIFLOZIN PD contains the active substance empagliflozin.

EMPAGLIFLOZIN PD is a member of a group of medicines called sodium-glucose co-transporter-2 (SGLT2) inhibitors.

EMPAGLIFLOZIN PD works by blocking the SGLT2 protein in your kidneys. This causes blood sugar (glucose) to be removed in your urine, thereby lowering the amount of sugar in your blood.
It is important that you continue with your diet and exercise plan as told to you by your health provider.

Type 2 diabetes mellitus

- EMPAGLIFLOZIN PD is used to treat type 2 diabetes in adult patients (aged 18 years and older) that cannot be controlled by diet and exercise alone**.**

What is type 2 diabetes?

Type 2 diabetes is a disease that comes from both your genes and your lifestyle. If you have type 2 diabetes, your pancreas does 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 glucose in your

blood which can lead to medical problems like heart disease, kidney disease, blindness, and poor circulation in your limbs.

Prevention of cardiovascular events

EMPAGLIFLOZIN PD is also used in adults with 'type 2 diabetes' with 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.

Heart failure

EMPAGLIFLOZIN PD is used to treat heart failure in adults with or without type 2 diabetes, to reduce the risk of cardiovascular death and to reduce hospitalisation for heart failure.
EMPAGLIFLOZIN PD also helps to slow down the worsening of kidney function.

Heart failure occurs when your heart is too weak or stiff and cannot work properly. This can lead to serious medical problems and need for hospital care. The most common symptoms of heart failure are feeling breathless, feeling tired or very tired all the time and ankle swelling.
EMPAGLIFLOZIN PD helps protect your heart from getting weaker and improves your symptoms.

Chronic kidney disease

EMPAGLIFLOZIN PD is used in adults with chronic kidney disease to reduce the risk of:

- progression of your kidney disease or death due to problems with your heart or blood vessels
- hospitalisation from any cause.

Chronic kidney disease is a long-term condition. It might be caused by other diseases such as diabetes and high blood pressure or even by your own immune system attacking the kidneys. When you have chronic kidney disease, your kidneys may gradually lose their ability to clean and filter your

blood properly. This can lead to serious medical problems such as swollen legs, heart failure or need for hospital care. EMPAGLIFLOZIN PD helps protect your kidneys from losing their function.

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

Do not take EMPAGLIFLOZIN PD:

- if you are hypersensitive (allergic) to empagliflozin or any of the other ingredients of EMPAGLIFLOZIN PD (see section 6)
- if you have type 1 diabetes mellitus (a chronic condition in which the pancreas produces little or no insulin)
- if you have been diagnosed with ketoacidosis (a serious complication of diabetes that occurs when your body produces high levels of blood acids called ketones)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with EMPAGLIFLOZIN PD:

- if you have type 1 diabetes (your body does not produce any insulin). EMPAGLIFLOZIN PD should not be used to treat 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. These symptoms could be a sign of "ketoacidosis" – a rare, but serious, sometimes life-threatening problem that occurs when your body produces high levels of blood acids called ketones in your urine or blood, as seen in blood tests.

  The risk of developing 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

- if you have an increase in the volume percentage of red blood cells in blood, measured as part of a blood test
- if you have serious kidney problems or are on renal dialysis. Your medical practitioner may limit your dose to 10 mg once a day or ask you to take a different medicine (see also section 3, 'How to take EMPAGLIFLOZIN PD). Your kidney function should be assessed before you start taking EMPAGLIFLOZIN PD, at least 6-monthly during treatment
- if you have liver problems
- if you are at increased risk of low blood pressure, such as patients with heart disease, have a history of low blood pressure, are taking medicines to treat high blood pressure or 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
- if you have been vomiting, 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 EMPAGLIFLOZIN PD 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 EMPAGLIFLOZIN PD until you have recovered
- if you have been diagnosed with heart failure (a chronic condition in which the heart doesn't pump blood as well as it should)
- talk to your medical practitioner 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, immediately inform your doctor. 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

- have symptoms of genital burning, redness, pain and discharge which may be signs of a genital infection.
- 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 healthcare professional
- because of how this medicine works, your urine will test positive for sugar while you are taking EMPAGLIFLOZIN PD
- if you are 75 years old or older as starting this medicine above 75 years is not recommended.

Children and adolescents

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

Other medicines and EMPAGLIFLOZIN PD

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

- if you are taking lithium (a mood stabilizing medicine used to treat certain mental illnesses). EMPAGLIFLOZIN PD can lower the amount of lithium in your blood.

EMPAGLIFLOZIN PD with food and drink

EMPAGLIFLOZIN PD can be taken with or without food.

Pregnancy, breastfeeding and fertility

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

Do not use EMPAGLIFLOZIN PD if you are pregnant. It is unknown if EMPAGLIFLOZIN PD is harmful to the unborn child. Do not use EMPAGLIFLOZIN PD if you are breastfeeding. It is not known if EMPAGLIFLOZIN PD passes into human breast milk.

Driving and using machines

EMPAGLIFLOZIN PD may influence the ability to drive and use machines. If you experience symptoms of low blood sugar, such as shaking, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion while taking EMPAGLIFLOZIN PD, do not drive or use machines and contact your healthcare provider immediately.

It is not always possible to predict to what extent EMPAGLIFLOZIN PD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EMPAGLIFLOZIN PD affects them.

EMPAGLIFLOZIN PD contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sodium

EMPAGLIFLOZIN PD contains less than 1 mmol sodium (0,023 g) per dose, that is to say essentially 'sodium-free'.

3. How to take EMPAGLIFLOZIN PD

Do not share medicines prescribed for you with any other person. Always take EMPAGLIFLOZIN PD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablet whole with water. You can take the tablet with or without food.

Type 2 Diabetes

The usual dose of EMPAGLIFLOZIN PD is one 10 mg tablet once a day. Your doctor will decide whether to increase your dose to 25 mg once a day, if needed to help to control your blood sugar. Check your blood sugar as your healthcare professional advises you to. Appropriate 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 EMPAGLIFLOZIN PD.

Heart failure or chronic kidney disease

The usual dose of EMPAGLIFLOZIN PD is one 10 mg tablet once a day.

Kidney disease:

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

Liver problems:

Talk to your doctor in case you suffer from severe liver disease as your doctor may need to adjust your dose of EMPAGLIFLOZIN PD.

Elderly:

There is very little experience in patients aged 85 years or older. Treatment with EMPAGLIFLOZIN PD should not be started in patients above the age of 85.

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.

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

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

If you take more EMPAGLIFLOZIN PD than you should

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

Symptoms of overdose may include:

- increased risk and severity of side effects as listed in section 4.

If you forget to take EMPAGLIFLOZIN PD

If you forget to take EMPAGLIFLOZIN PD, take as soon as you remember, on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking EMPAGLIFLOZIN PD

Do not stop taking EMPAGLIFLOZIN PD without first consulting your doctor. If you have type 2 diabetes mellitus, your blood sugar levels may increase when you stop taking EMPAGLIFLOZIN PD.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

EMPAGLIFLOZIN PD can have side effects.
Not all side effects reported for EMPAGLIFLOZIN PD are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using EMPAGLIFLOZIN PD, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to EMPAGLIFLOZIN PD. 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:

- diabetic ketoacidosis (symptoms include: rapid weight loss, nausea and vomiting, stomach pain excessive thirst, rapid 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)
- 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.
- have symptoms of genital burning, redness, pain and discharge which may be signs of a genital infection.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- genital yeast infection like thrush, inflamed nose or throat, (nasopharyngitis), cough
- sepsis caused by a urogenital tract infection (urosepsis), inflammation of the kidney as a result of bacterial infection (pyelonephritis)

- low blood sugar (hypoglycaemia) when taken with other antidiabetic medicines, with symptoms that include shaking, sweating, feeling very anxious or confused, fast heartbeat, excessive hunger, headache
- weight loss, high cholesterol levels in your blood
- excess of sugar in the urine, increased urination
- rash, itching
- thirst
- constipation.

Less frequent side effects:

- dehydration (with symptoms that may include unusual thirst, light-headedness or dizziness upon standing, fainting or loss of consciousness), low blood pressure
- hives (reddened, itchy welts), swelling of the area beneath the skin or mouth
- pain or a burning sensation when urinating, 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), increased urination (if you have heart failure).
- urine tests indicating sugar in urine in heart failure patients

The following side effects have been reported but the frequency for them to occur is not known:

- phimosis (a tight foreskin that cannot be fully retracted to expose the head of the penis) with symptoms that may include pain, redness, or swelling of the foreskin, discharge from the foreskin, white ring or scar tissue around the opening of the foreskin, pain or burning sensation during urination, bulging of the foreskin during urination.

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 or pharmacist. You can also report side effects to 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 EMPAGLIFLOZIN PD. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store EMPAGLIFLOZIN PD

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep container well closed. Protect from light and moisture.

Do not use after the expiry date stated on the carton.

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 EMPAGLIFLOZIN PD contains:

The active substance is empagliflozin.

EMPAGLIFLOZIN 10 mg PD: Each film coated tablet contains empagliflozin 10 mg.

EMPAGLIFLOZIN 25 mg PD: Each film coated tablet contains empagliflozin 25 mg.

The other ingredients are:

Tablet cores:

Croscarmellose sodium, colloidal silicon dioxide, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

Film coating (Opadry Yellow)

HPMC (hypromellose), iron oxide yellow, macrogol /PEG, titanium dioxide.

What EMPAGLIFLOZIN PD looks like and contents of the pack

EMPAGLIFLOZIN 10 mg PD: Pale yellow, round, debossed with “L75” on one side and the other side plain, film coated tablets.

EMPAGLIFLOZIN 25 mg PD: Pale yellow, oval, debossed with ‘LU’ on one side and ‘E65’ on the other side, film coated tablets.

EMPAGLIFLOZIN PD tablets are available in:

EMPAGLIFLOZIN 10 mg PD:

30, 60 and 90 tablets: 50 ml round opaque white, 33 mm neck HDPE bottles, with a child resistant cap and printed heat-seal liner containing 30, 60 or 90 tablets in a printed carton.

500 tablets: 60 ml round opaque white, 33 mm neck HDPE bottles, with a child resistant cap and printed heat-seal liner containing 500 tablets. Not all pack sizes are marketed.

EMPAGLIFLOZIN 25 mg PD:

30, 60 and 90 tablets: 50 ml round opaque white, 33 mm neck HDPE bottles, with a child resistant cap and printed heat-seal liner containing 30, 60 or 90 tablets in a printed carton.

500 tablets: 150 ml round opaque white, 38 mm neck HDPE bottles, with a child resistant cap and printed heat-seal liner containing 500 tablets. Not all pack sizes are marketed.

Holder of Certificate of Registration

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