PACKAGE LEAFLET

Package leaflet: Information for the patient

Emlygexa 10 mg film-coated tablets
empagliflozin

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 Emlygexa is and what it is used for
2. What you need to know before you take Emlygexa
3. How to take Emlygexa
4. Possible side effects
5. How to store Emlygexa
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1. What Emlygexa is and what it is used for

What Emlygexa is
Emlygexa contains the active substance empagliflozin. Empagliflozin is a member of a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors.

What Emlygexa is used for

Type 2 diabetes mellitus
- Emlygexa is used to treat type 2 diabetes in adults and children aged 10 years and older that cannot be controlled by diet and exercise alone.
- Emlygexa can be used without other medicines in patients who cannot take metformin (another diabetes medicine).
- Emlygexa 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 works by blocking the SGLT2 protein in your kidneys. This causes blood sugar (glucose) to be removed in your urine. Thereby empagliflozin lowers the amount of sugar in your blood.

This medicine can also help prevent heart disease in patients with type 2 diabetes mellitus.

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

Heart failure
- Emlygexa is used to treat heart failure in adult patients with symptoms due to impaired heart function.

Chronic kidney disease
- Emlygexa is used to treat chronic kidney disease in adult patients.

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.

What is heart failure?
Heart failure occurs when the 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.

Emlygexa helps protect your heart from getting weaker and improves your symptoms.

What is chronic kidney disease?
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 the blood properly. This can lead to serious medical problems such as swollen legs, heart failure or need for hospital care.

Emlygexa helps protect your kidneys from losing their function.

2. What you need to know before you take Emlygexa

Do not take Emlygexa
- if you are allergic to empagliflozin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Contact a doctor or the nearest hospital straight away:

Ketoacidosis
- 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 serious, sometimes life-threatening problem you can get because of increased levels of "ketone bodies" in your urine or blood, seen in 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 suspect you have ketoacidosis, contact a doctor or the nearest hospital straight away and stop taking this medicine until further advice from your doctor.

Talk to your doctor, pharmacist or nurse 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 Emlygexa if you have type 1 diabetes.
- if you have serious kidney problems – your doctor 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 Emlygexa").
- if you have serious liver problems – your doctor may ask you to take a different medicine.
- might be at risk of dehydration, for example:
  - if you are being sick, have diarrhoea or fever, or if you are not able to eat or drink
  - if you are taking medicines that increase urine production [diuretics] or lower blood pressure
  - if you are 75 years old or older.

Possible signs are listed in section 4 under "dehydration". Your doctor may ask you to stop taking Emlygexa until you recover to prevent loss of too much body fluid. Ask about ways to prevent dehydration.
- if you have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking Emlygexa 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 professional.

Kidney function
Your kidneys should be checked before you start taking and whilst you are on this medicine.

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

Children and adolescents
Emlygexa can be used in children aged 10 years and older for the treatment of type 2 diabetes. No data are available in children below 10 years of age.

Emlygexa is not recommended for children and adolescents under 18 years of age for the treatment of heart failure or for the treatment of chronic kidney disease, because it has not been studied in these patients.

Other medicines and Emlygexa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
It is important to tell your doctor:
- if you are taking medicines that increase urine production (diuretics). Your doctor may ask you to stop taking Emlygexa. Possible signs of losing too much fluid from your body are listed in section 4.
- if you are taking other 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).
- if you are taking lithium because Emlygexa can lower the amount of lithium in your blood.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not use Emlygexa if you are pregnant. It is unknown if empagliflozin is harmful to the unborn child. Do not use Emlygexa if you are breast-feeding. It is not known if empagliflozin passes into human breast milk.

Driving and using machines
Emlygexa has minor influence on the ability to drive and use machines.

Taking this medicine 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 drive or

use any tools or machines, if you feel dizzy while taking Emlygexa.

Emlygexa contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".

3. How to take Emlygexa

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

How much to take
- The recommended dose of Emlygexa is one 10 mg tablet once a day. If you have type 2 diabetes mellitus, your doctor will decide whether to increase your dose to 25 mg once a day, if needed to help to control your blood sugar.
- Your doctor may limit your dose to 10 mg once a day if you have a kidney problem.
- Your doctor will prescribe the strength that is right for you. Do not change your dose unless your doctor has told you to.

Taking this medicine
- Swallow the tablet whole with water.
- You can take the tablet 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.

If you have type 2 diabetes mellitus, your doctor may prescribe Emlygexa together with another diabetes 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 use its blood sugar better. It is important to stay on the diet and exercise program recommended by your doctor while taking Emlygexa.

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

If you forget to take Emlygexa
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 Emlygexa 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 to make up for a forgotten dose.

If you stop taking Emlygexa
Do not stop taking Emlygexa without first consulting your doctor, unless you suspect you have ketoacidosis (see “ketoacidosis” under “warnings and precautions”). If you have type 2 diabetes mellitus, your blood sugar levels may increase when you stop taking Emlygexa.

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:

Severe allergic reaction, seen uncommonly (may affect up to 1 in 100 people)
Possible signs of severe allergic reaction may include:
- swelling of the face, lips, mouth, tongue, or throat that may lead to difficulty breathing or swallowing)

Ketoacidosis, seen uncommonly (may affect up to 1 in 100 people)
These are the signs of 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 Emlygexa.

Contact your doctor as soon as possible if you notice the following side effects:

Low blood sugar (hypoglycaemia), seen very commonly (may affect more than 1 in 10 people)
If you take Emlygexa with another medicine that can cause low blood sugar, such as a sulphonylurea or insulin, your risk of getting low blood sugar is higher. The signs of 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 (may affect up to 1 in 10 people)
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 Emlygexa works, but they can also be signs of urinary tract infection. If you note an increase in such symptoms, you should also contact your doctor.

Dehydration, seen very commonly (may affect more than 1 in 10 people)
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 Emlygexa:
Common
- genital yeast infection (thrush)
- passing more urine than usual or needing to pass urine more often

- itching
- rash or red skin – this may be itchy and include raised bumps, oozing fluid or blisters
- thirst
- blood tests may show an increase in blood fat (cholesterol) levels in your blood
- constipation

Uncommon
- hives
- straining or pain when emptying the bladder
- 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)

Rare
- 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

Very Rare
- inflammation of the kidneys (tubulointerstitial nephritis)

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. You can also report side effects directly via the ADR Reporting Website: https://medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emlygexa

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.

This medicine does not require any special storage conditions.

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 Emlygexa contains
- The active substance is empagliflozin.
  Each film-coated tablet contains 10 mg empagliflozin.
- The other ingredients (excipients) are:
  Tablet core: microcrystalline cellulose, mannitol (E 421), povidone, croscarmellose sodium, magnesium stearate and colloidal anhydrous sillica.
  Film coating: hypromellose, titanium dioxide (E 171), talc, propylene glycol and yellow iron oxide (E 172).
  See section 2 " Emlygexa contains sodium".

What Emlygexa looks like and contents of the pack
Light brownish yellow, round (7 mm in diameter), biconvex film-coated tablet (tablet), debossed with “10” on one side.

Emlygexa is available in packs containing:
- 10, 14, 15, 28, 30, 60, 70, 90 and 100 film-coated tablets in blisters,
- 10 × 1, 14 × 1, 15 × 1, 28 × 1, 30 × 1, 60 × 1, 70 × 1, 90 × 1 and 100 × 1 film-coated tablet in perforated unit dose blisters.
- 14 × 1 and 28 × 1 film-coated tablet in perforated unit dose blisters, calendar packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Bulgaria	Emlygexa 10 mg филмирани таблетки
Czech Republic	Emlygexa
Estonia	Emlygexa
Greece	Emlygexa
Croatia	Emlygexa 10 mg filmom obložene tablete
Hungary	Emlygexa 10 mg filmtabletta
Lithuania	Emlygexa 10 mg plėvele dengtos tabletės
Latvia	Emlygexa 10 mg apvalkotās tablets
Poland	Emlygexa
Romania	Emlygexa 10 mg comprimate filmate
Slovenia	Emlygexa 10 filmsko obložene tablete
Slovakia	Emlygexa 10 mg filmom obalené tablety

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