**Package leaflet: Information for the user**

# Empagliflozin 10 mg film-coated tablets
# Empagliflozin 25 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

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


## 1. What Empagliflozin is and what it is used for

**What Empagliflozin is**
Empagliflozin film-coated tablets contain the active substance empagliflozin.

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

**What Empagliflozin is used for**
**Type 2 diabetes mellitus**
- Empagliflozin 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.
- Empagliflozin can be used without other medicines in patients who cannot take metformin (another diabetes medicine).
- Empagliflozin 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 or pharmacist.

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

**Chronic kidney disease**
- Empagliflozin 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.

Empagliflozin 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.

Empagliflozin helps protect your kidneys from losing their function.

## 2. What you need to know before you take Empagliflozin

**Do not take Empagliflozin**
- 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 or pharmacist 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 empagliflozin 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 Empagliflozin’).
- 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 empagliflozin 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 empagliflozin 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**
Empagliflozin can be used in children aged 10 years and older for the treatment of type 2 diabetes. No data is available for children below 10 years of age.

Empagliflozin 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 Empagliflozin**
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 empagliflozin. 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 empagliflozin 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 empagliflozin if you are pregnant. It is unknown if empagliflozin is harmful to the unborn child. Do not use empagliflozin if you are breast-feeding. It is not known if empagliflozin passes into human breast milk.

**Driving and using machines**
Empagliflozin 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 empagliflozin.

**Important information about the ingredients of Empagliflozin film-coated tablets:**
*lactose:*
Empagliflozin film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

*Information on sodium content:*
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say is essentially ‘sodium -free’.

## 3. How to take Empagliflozin

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 recommended dose of empagliflozin 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.

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Version: 01
Date & Time: 11.08.2026 & 3.40 PM
Submission Code: N26169_u3

- 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 empagliflozin 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 empagliflozin.

**If you take more Empagliflozin than you should**
If you take more empagliflozin 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 Empagliflozin**
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 empagliflozin 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 empagliflozin to make up for a forgotten dose.

**If you stop taking Empagliflozin**
Do not stop taking empagliflozin 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 empagliflozin.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 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 empagliflozin.

**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 empagliflozin 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 empagliflozin 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 Empagliflozin:**
Common (may affect up to 1 in 10 people):
- 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 (may affect up to 1 in 100 people):
- 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 (may affect up to 1 in 1 000 people):
- 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 (may affect up to 1 in 10 000 people):
- inflammation of the kidneys (tubulointerstitial nephritis).

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Empagliflozin

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

- The active substance is empagliflozin

What Empagliflozin 10 mg film-coated tablets contain:
Each film-coated tablet contains 10 mg of empagliflozin.

What Empagliflozin 25 mg film-coated tablets contain:
Each film-coated tablet contains 25 mg of empagliflozin.

- **The other ingredientse are:**

*Tablet core*
Lactose monohydrate
Cellulose microcrystalline (Grade-101)
Croscarmellose sodium
Copovidone (K-28)
Silica, colloidal anhydrous
Magnesium stearate

*Tablet coating*
Hypromellose 2910 (E464)
Titanium dioxide (E171)
Macrogol 6000 (E1521)
Talc (E553b)
Iron oxide yellow (E172)

**What Empagliflozin film-coated tablets looks like and contents of the pack**
Film-coated tablet

***Empagliflozin 10 mg film-coated tablets***
Pale yellow, round, biconvex, approximately 5.2mm, film-coated tablets debossed with "EI" on one side and "I0" on the other side.

***Empagliflozin 25 mg film-coated tablets***
Pale yellow, oval, approximately 11.1mm × 5.1mm, film-coated tablets debossed with "EI" on one side and "25" on the other side.

Empagliflozin film-coated tablets are available in Clear PVC/Aluminium foil blister pack.

**Pack sizes:**
7, 10, 14, 28, 30, 56, 60, 70, 90, 98, 100 and 120 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing authorization holder**
Milpharm Limited
1 Roundwood Avenue,
Stockley Park,
Uxbridge, UB11 1AF
United Kingdom

**Manufacturer**
APL Swift Services (Malta) Ltd
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**This leaflet was last revised in 08/2026.**

**Ref Ver: 01**

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