

Direct Healthcare Professional Communication (DHPC)

15 February 2026

Empagliflozin SPC 10 mg and 25 mg - Film-Coated Tablets - Important Information Regarding Packaging.

Dear Healthcare professional,

Sudair Pharma Company, in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you of the following:

Summary

- **Multiple complaints have been received regarding difficulty in tablet extraction from the currently marketed alu-paper blister packaging.**
- **Investigation confirmed that there is no defect in product quality, stability, or efficacy.**
- **The issue is related to handling and extraction technique.**
- **A card for tablet extraction instructions has been created to be distributed to all health care facilities for previously distributed products.**
- **Updated tablet extraction instructions have been added to the Patient Information Leaflet (PIL) for ongoing products supply.**
- **To permanently mitigate this usability issue, Sudair Pharma will initiate a variation to replace the alu-paper blister packaging with standard alu-alu blister packaging for future batches.**
- **No recall is required.**

Further information on the concern and the recommendations

- Following distribution of Empagliflozin SPC 10 mg and 25 mg in alu-paper blister packaging, Sudair Pharma Company and SFDA received multiple product complaints from patients and healthcare professionals concerning difficulty in extracting tablets from the blister cavity.
- The issue was determined to be related to usability and insufficient clarity of extraction instructions.
- No causal relationship with adverse drug reactions has been established.
- The DHPC is being disseminated to proactively mitigate potential medication-use errors and ensure optimal patient use during the transition period.

Advice for Healthcare Professionals

- Counsel patients on the appropriate method of tablet extraction from the current blister packaging.
- Continue prescribing and dispensing the product as usual, as no recall or suspension is required.

Placing the risk in the context of the benefit

- Empagliflozin SPC 10 mg and 25 mg remains an effective and authorized treatment for Type 2 diabetes mellitus, heart failure & chronic kidney disease.
- The identified issue relates solely to packaging usability and does not affect product quality, safety, or efficacy.

Call for reporting

Healthcare professionals are reminded of the importance of reporting suspected adverse drug reactions and product complaints through the following contact details:

- To Saudi Food and Drug Authority (SFDA):
 - Website: <https://ade.sfda.gov.sa>
 - SFDA Call Center: 19999
 - E-mail: npc.drug@sfda.gov.sa
- To Sudair Pharma Company:
 - Website: <https://sudairpharma.com/>
 - Phone: +966-920001432 Ext. 107
 - Email: Pharmacovigilance@SudairPharma.com

Sincerely,
Soliman Alzahrani
Pharmacovigilance Manager



Annexes

- Patient instruction cards.
- Patient Information Leaflet (PIL).

Empagliflozin SPC

Empagliflozin 10 mg and 25 mg
Film-Coated Tablets

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

1. What this product is and what it is used for

- A. What Empagliflozin SPC is**
Empagliflozin SPC contains the active substance empagliflozin. Empagliflozin is a member of a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors.
- B. What Empagliflozin SPC is used for Type 2 diabetes mellitus**
Empagliflozin SPC is used to treat type 2 diabetes in adult patients (aged 18 years and older) that cannot be controlled by diet and exercise alone.
- Empagliflozin SPC can be used without other medicines in patients who cannot take metformin (another diabetes medicine).
 - Empagliflozin SPC 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 SPC works by blocking the SGLT2 protein in your kidneys. This causes blood sugar (glucose) to be removed in your urine. Thereby Empagliflozin SPC 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

- Empagliflozin SPC is used to treat heart failure in adult patients with symptoms due to impaired heart function. It also helps to slow down worsening of kidney function in those patients. It may be used whether or not you have type 2 diabetes mellitus.

Chronic kidney disease

- Empagliflozin SPC 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 SPC 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 hypertension 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 SPC helps protect your kidneys from losing their function.

2. What you need to know before you use this product

Do not take Empagliflozin SPC

- 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.

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 Empagliflozin SPC 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 SPC').
- 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 SPC 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 SPC 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 SPC is not recommended for children and adolescents under 18 years, because it has not been studied in these patients.

Other medicines and Empagliflozin SPC

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

Driving and using machines

Empagliflozin SPC 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 SPC.

Empagliflozin SPC contains lactose monohydrate and sodium

Lactose monohydrate

Empagliflozin SPC contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium

Empagliflozin SPC contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

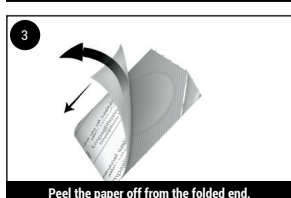
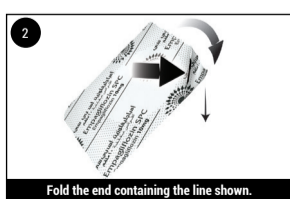
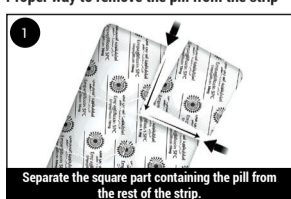
3. How to use this product.

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 SPC 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.

Proper way to remove the pill from the strip



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 SPC 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 SPC.

If you take more Empagliflozin SPC than you should

If you take more Empagliflozin SPC 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 SPC

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 SPC 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 SPC to make up for a forgotten dose.

If you stop taking Empagliflozin SPC

Do not stop taking Empagliflozin SPC without first consulting your doctor. If you have type 2 diabetes mellitus, your blood sugar levels may increase when you stop taking Empagliflozin SPC.

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 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

- 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).

5. How to store Empagliflozin SPC

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Store in the original package.

Do not use this medicine after the expiry date which is stated on the package after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

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 Empagliflozin SPC contains

The active ingredient is empagliflozin.

Each film-coated tablet of Empagliflozin SPC 10 mg Film-coated Tablets contains 10 mg empagliflozin.

Each film-coated tablet of Empagliflozin SPC 25 mg Film-coated Tablets contains 25 mg empagliflozin.

The other ingredients are: Copovidone, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate and Opadry white OY-58900.

What Empagliflozin SPC looks like and contents of the pack

Empagliflozin SPC 10 mg Film-coated Tablets are white to off-white, round, biconvex film-coated tablets, debossed with '590' on one side and plain on the other side in blisters.

Empagliflozin SPC 25 mg Film-coated Tablets are white to off-white, oval, biconvex film-coated tablets, debossed with '591' on one side and plain on the other side in blisters.

Pack size: 30 Film-coated Tablets.

Marketing Authorization Holder and Manufacturer

Sudair Pharma Company (SPC),
King Fahad Branch Road, King Fahad District,
Riyadh Gallery Mall, A1 Offices Building,
Third Floor, Office 305-A,
P.O. Box 12262, Riyadh 7639, Saudi Arabia
Tel: +966-11-920001432
Fax: +966-11-4622230
Email: info@sudairpharma.com

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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 (see details below). By reporting side effects, you can also help provide more information on the safety of this medicine.

• Saudi Arabia

- The National Pharmacovigilance Centre (NPC)
- SFDA Call Center: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: <https://ade.sfd.gov.sa>

• United Arab of Emirates

- Pharmacovigilance & Medical Device Section
- P.O. Box: 1853
- Tel: 80011111
- e-mail: pv@moh.gov.ae
- Drug Department
- Ministry of Health & Prevention
- Dubai

• Other GCC States

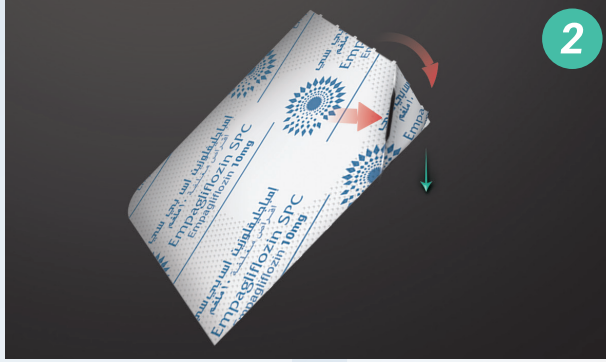
- Please contact the relevant competent authority.

• This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists



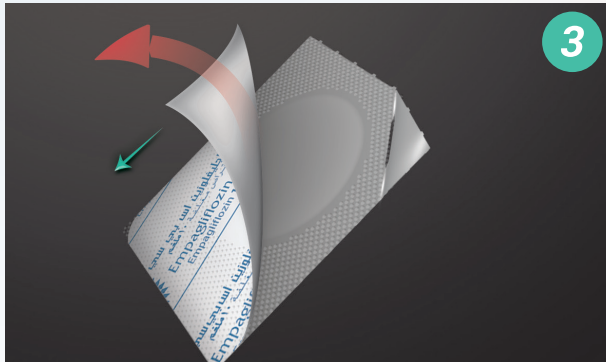
2. Fold the end containing the line shown.

٢. اثن الطرف المحتوي على الخط الموضح.



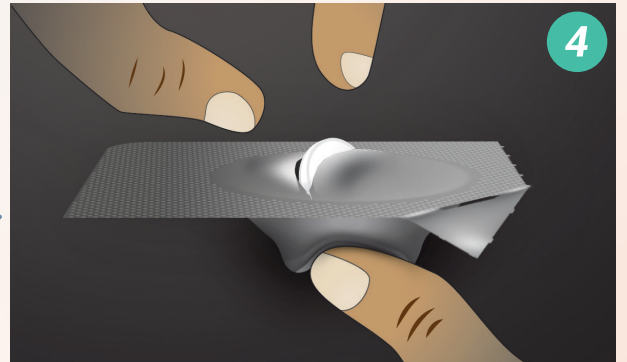
1. Separate the square part containing the pill from the rest of the strip.

١. افصل الجزء المربع المحتوي على الحبة عن باقي الشريط.



3. Peel the paper off from the folded end.

٣. اذنع كامل الورقة البيضاء من الطرف المثني.



4. Press the pill to pop it out.

٤. اضغط على الحبة من الأسفل لإخراجها.

Please report suspected adverse event:

Saudi Food and Drug Authority (SFDA) via: Website: <https://ade.sfgda.gov.sa>, Email: npc.drug@sfgda.gov.sa, Call center: 19999
Sudair Pharma: Telephone on: +920001432-966 ext.107, Email: pharmacovigilance@sudairpharma.com

للإبلاغ عن الآثار الجانبية
إبلاغ الهيئة العامة للغذاء والدواء عن أي أعراض جانبية: الموقع عبر الإنترنت: <https://ade.sfgda.gov.sa>, البريد الإلكتروني: npc.drug@sfgda.gov.sa, مركز الاتصال: ١٩٩٩٩
يرجى أيضاً إبلاغ سديرفارما هاتفياً على الرقم: +٩٦٦ ٩٢٠٠٠١٤٣٢ داخلي ١٠٧، أو عبر البريد الإلكتروني: pharmacovigilance@sudairpharma.com.

إمباجل يفلوزين

إمباجل يفلوزين ١٠ ملغم، ٢٥ ملغم أس بي سي

خطوات إخراج الحبة من الشريط



EMPAGLIFLOZIN

Empagliflozin 10mg, 25mg SPC

Steps to remove the pill from the strip

