

Package leaflet: Information for the patient

Empazimet 5 mg/1000 mg Film-Coated Tablets

Empazimet 12.5 mg/1000 mg Film-Coated Tablets

Empagliflozin / Metformin hydrochloride

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.

What is in this leaflet

- What Empazimet is and what it is used for
- What you need to know before you take Empazimet
- How to take Empazimet
- Possible side effects
- How to store Empazimet
- Contents of the pack and other information

1. What Empazimet is and what it is used for

What Empazimet is

Empazimet contains two active substances empagliflozin and metformin. Each belongs to a group of medicines called “oral anti-diabetics”. These are medicines taken by mouth to treat type 2 diabetes.

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 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.

How Empazimet works

Empagliflozin belongs to a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors. It works by blocking the SGLT2 protein in your kidneys. This causes blood sugar (glucose) to be removed in your urine. Metformin works in a different way to lower blood sugar levels, mainly by blocking glucose production in the liver.

Thereby Empazimet lowers the amount of sugar in your blood. This medicine can also help prevent heart disease.

What Empazimet is used for

Empazimet is added to diet and exercise to treat type 2 diabetes in adult patients (aged 18 years and older) whose diabetes cannot be controlled by adding metformin alone or metformin with other medicines for diabetes.

Empazimet can also be combined with other medicines for the treatment of diabetes. These may be medicines taken by mouth or given by injection such as insulin.

In addition, Empazimet can be used as an alternative to taking both empagliflozin and metformin as single tablets. To avoid overdose, do not continue taking empagliflozin and metformin tablets separately, if you are taking this medicine.

It is important that you continue to exercise as planned as told by your doctor, pharmacist.

2. What you need to know before you take Empazimet

Do not take Empazimet

- if you are allergic to empagliflozin, metformin or any of the other ingredients of this medicine (listed in section 6);
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (very high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see ‘Risk of lactic acidosis’ below) or ketoacidosis. Ketoacidosis is a condition in which substances called ‘ketone bodies’ accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell;
- if you have had a diabetic pre-coma;
- if you have severely reduced kidney function;
- if you have a severe infection such. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see ‘Warnings and precautions’);
- if you have lost a lot of water from your body (dehydration). Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see ‘Warnings and precautions’);
- if you are treated for or have recently had a heart attack, have severe problems with your circulation (such as shock) or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see section ‘Warnings and precautions’);
- if you have problems with your liver;
- if you drink large amounts of alcohol, either every day or only from time to time (see section ‘Empazimet with alcohol’).

Warnings and precautions

Risk of lactic acidosis Empazimet may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

Stop taking Empazimet for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop taking Empazimet and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

Talk to your doctor, pharmacist or doctor before taking this medicine, and during treatment:

- 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 “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;
- if you have “type 1 diabetes” – this type usually starts when you are young and your body does not produce any insulin. Empazimet should not be used to treat patients with type 1 diabetes;
- 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 over 75 years old

Possible signs are listed in section 4 under ‘dehydration’. Your doctor may ask you to stop taking Empazimet until you recover to prevent loss of too much body fluid.

- if you are 85 years old or older as you should not start taking Empazimet due to limited therapeutic experience;
- if you have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking Empazimet until you have recovered;
- if you need to undergo an examination with iodination contrast agents (such as X-ray or scan). More information is given below in “Other medicines and Empazimet”.

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.

Surgery

If you need to have major surgery you must stop taking Empazimet during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Empazimet.

Kidney function

During treatment with Empazimet, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

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.

Urine glucose

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

Children and adolescents

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

Other medicines and Empazimet

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Empazimet before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Empazimet.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or you may need to adjust the dosage of Empazimet. It is especially important to mention the following:

- Medicines which increase urine production (diuretics), as Empazimet may increase the risk of losing too much fluid. Your doctor may ask you to stop taking Empazimet. Possible signs of losing too much fluid from your body are listed in section 4.
- 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).
- Medicines that may change the amount of metformin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, zytosin, olaparib).
- Bronchodilators (beta-2 agonists) which are used to treat asthma.
- Corticosteroids (given by mouth, as an injection, or inhaled), which are used to treat inflammation in diseases like asthma and arthritis.
- Medicines used to treat pain and inflammation (NSAID and COX-2 inhibitors).
- Certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).
- Medicines that contain alcohol (see section ‘Empazimet with alcohol’).
- Iodinated contrast agents (medicines used during an X-ray, see section ‘Warnings and precautions’.

Empazimet with alcohol

Avoid excessive alcohol intake while taking Empazimet since this may increase the risk of lactic acidosis (see section ‘Warnings and precautions’).

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 take Empazimet if you are pregnant. It is unknown if this medicine is harmful to the unborn child.

Metformin passes into human milk in small amounts. It is not known whether empagliflozin passes into human breast milk. Do not take Empazimet if you are breast-feeding.

Driving and using machines

Empazimet 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 Empazimet.

3. How to take Empazimet

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 dose of Empazimet varies depending on your condition and the doses of diabetes medicines you currently take. Your doctor will adjust your dose as necessary and tell you exactly which strength of the medicine to take.

The recommended dose is one tablet twice a day. Your doctor will normally start Empazimet treatment by prescribing the strength of tablet that supplies the same dose of metformin you are already taking (850 mg or 1,000 mg twice a day), and the lowest dose of empagliflozin (5 mg twice a day). If you are already taking both medicines separately, your doctor will start treatment with tablets of Empazimet that will supply the same amount of both. If you have reduced kidney function, your doctor may prescribe a lower dose.

Taking this medicine

Swallow the tablet whole with water.

- Take the tablets with meals to lower your chance of an upset stomach.
- Take the tablet twice daily by mouth.

Your doctor may prescribe Empazimet together with another diabetes medicine. Remember to take all medicines as directed by your doctor to achieve the best results for your health. Your doctor may need to adjust your doses to control your blood sugar.

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 Empazimet.

If you take more Empazimet than you should

If you take more Empazimet tablets than you should have, you may experience lactic acidosis (see section 2 ‘symptoms of Lactic acidosis’).

If you forget to take Empazimet

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of this medicine.

If you stop taking Empazimet

Do not stop taking Empazimet without first consulting your doctor. Your blood sugar levels may increase when you stop taking Empazimet. 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 with unknown frequency (frequency cannot be estimated from the available data)

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)
- Lactic acidosis, seen very rarely (may affect up to 1 in 10,000 people)

Empazimet may cause a very rare but very serious side effect called lactic acidosis (see section 2). If this happens you may stop taking Empazimet and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

Diabetic ketoacidosis, seen rarely (may affect up to 1 in 1,000 people).

For signs of diabetic ketoacidosis (see section 2).

This may occur regardless of blood glucose level. Your doctor may decide to temporarily or permanently stop your treatment with Empazimet. 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 Empazimet with another medicine that can cause low blood sugar, such as a sulphonylurea or insulin, your risk of getting low blood sugar is increased. The signs of low blood sugar may include:

- shaking, sweating, feeling very anxious or confused, fast heartbeat, 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 moin may be due to the way Empazimet works, but they can also be signs of urinary tract infection. If you get any an increase in such symptoms, you should also contact your doctor.

Dehydration, seen uncommonly (may affect up to 1 in 100 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 Empazimet:

Very common

- feeling sick (nausea), vomiting, diarrhoea or stomach ache, loss of appetite
- 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
- changes to the way things taste, thirst
- blood tests may show an increase in blood fat (cholesterol) levels in your blood

Uncommon

- hives, stinging or pain when emptying the bladder
- blood tests may show a decrease in kidney function (creatinine or urea), and/or an increase in the amount of red blood cells in your blood (haematocrit)

Very rare

- decreased vitamin B12 levels in the blood, abnormalities in liver function tests, inflammation of the liver (hepatitis), redness of the skin (erythema)
- Not known

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

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Empazimet

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 outer packaging. The expiry date refers to the last day of that month.

- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Empazimet contains

The active substances are empagliflozin and metformin.

Each Empazimet 5 mg/1000 mg film-coated tablet contains 5 mg empagliflozin and 1000 mg metformin hydrochloride.

Each Empazimet 12.5 mg/1000 mg film-coated tablet (tablet) contains 12.5 mg empagliflozin and 1000 mg metformin hydrochloride.

The other ingredient(s) is/are:

Copolyolone, Crosscarmellose sodium, Pregelatinized starch, Colloidal silica anhydrous, Magnesium stearate, Hypromellose, Titanium dioxide, Polyethylene glycol and Hydroxypropyl cellulose.

Empazimet 5 mg/1000 mg film-coated tablet contains FD&C yellow 5. Empazimet 12.5 mg/1000 mg tablets contains Red iron oxide and FD&C blue No.1.

What Empazimet looks like and contents of the pack

Empazimet 5mg/1000mg tablets are yellow, oblong, non-scored, film-coated tablets.

Empazimet 12.5mg/1000mg are purple, oblong, non-scored, film-coated tablets.

Empazimet tablets are available in six PVC/PVDC opaque/Alu blisters (10 tablets per blister) packed in a carton box with a leaflet.

Not all strengths may be marketed.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. - Lebanon

P.O Box 39201 Jdeidet-El-Metn, Lebanon

Contact us: pharmaline@malingroup.com

Company website: www.pharmaline.com.lb

Reg. No.: Empazimet 5 mg/1000 mg, Lebanon: 21022/1

Reg. No.: Empazimet 12.5 mg/1000 mg, Lebanon: 20922/1

This is a medicament

A 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 experts in medicine, its 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.

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Council of Arab Health Ministers

Union of Arab Pharmacists

نشرة الدواء: معلومات للمريض

إمبازيميت أقراص 5 ملغ/ ١٠٠٠ ملغ مغلفة بالفلم

إمبازيميت أقراص ١٢.٥ ملغ/ ١٠٠٠ ملغ مغلفة بالفلم

إمبازيفلوزين / هيدروكلوريد الميتفورمين

إفراؤه نشطرة الكالسيوم بعناية قبل القيام بتناول هذا الدواء حيث أنها تحتوي على معلومات مهمة لك

-احتفظ بهذه النشرة فقد تحتاج إليها ألاماً

-في حال وجود أي أسئلة أو لديك بعض استشارة الطبيب المعالج أو الصيدلي

-قد وصف هذا الدواء لك شخصياً ولا ينبغي لك أن تخطئه لأحد آخر حتى ولو ظهرت عليه نفس أعراض مرضك فقد يؤدي ذلك إلى الإضرار به

-لا تتحدث بأي شيء خاصية غير المذكورة في هذه النشرة لأحد الطبيب المعالج أو الصيدلي

ما هي أعراض هذه الحالة؟

١. ما هو إمبازيميت وما هي دواعي استعماله

٢. ما الذي يجب عليك معرفته قبل تناول إمبازيميت

٣. ما هي طريقة تناول إمبازيميت

٤. الأعراض الجانبية المحتملة

٥. طريقة تخزين إمبازيميت

٦. احتياطات الدواء ومعلومات إضافية أخرى

١. ما هو إمبازيميت وما هي دواعي استعماله

ما هو إمبازيميت

يحتوي إمبازيميت على مادتين فعالتين وهما إمبازيفلوزين وميتفورمين. ينتمي كل منهما إلى مجموعة من الأدوية تسمى “الأدوية الفموية الحافظة للسكر الدم”. يتم تناول هذه الأدوية عن طريق الفم لمعالجة داء السكري من النوع ٢.

ما هو داء السكري من النوع ٢؟

إن داء السكري من النوع ٢ مرض مزمن ناتج عن جيناتك ونمط حياتك. إذا كنت تعاني من داء السكري من النوع ٢، يعني أن البنكرياس لا ينتج كمية كافية من الأنسولين لضغط مستوى الجلوكوز في الدم فيصبح جسمك غير قادر على استخدام الأنسولين الذي ينتجه بشكل فعال. يؤدي هذا الأمر إلى ارتفاع مستويات الجلوكوز في الدم وبالتالي إلى مشاكل صحية مثل الأمراض التي تسببها هذا المرض وضعف البؤرة العينية وضعف البؤرة العينية في أطرافك.

كيف يعمل إمبازيميت

ينتمي إمبازيفلوزين إلى الأدوية التي تُسمى مثبطات النقل المشترك صوديوم-جلوكوز ٢ أي مثبطات SGLT٢. يحجب هذا الدواء بروتين SGLT٢ في كليتيك مما يؤدي إلى التخلص من سكر الدم (الجلوكوز) عن طريق البول. يعمل الميتفورمين بطريقة مختلفة لتخفيض مستويات السكر في الدم من خلال منع إنتاج الكبد من إنتاج الجلوكوز.

وبالتالي، يمكن أن يساعد إمبازيميت في خفض مستوى السكر في الدم ويساعد أيضاً في الوقاية من الأمراض القلبية.

ما هي دواعي استعمال إمبازيميت

يتم استخدام إمبازيميت في جانب نظام غذائي وتغيير نمط الحياة بالإضافة إلى العلاج بالأنسولين في المرضى البالغين (٨ سنة وما فوق) الذين يعانون من مرض السكري الذي لا يمكن السيطرة عليه من خلال تناول الميتفورمين ومزيداً أو الميتفورمين إلى جانب أدوية أخرى لعلاج مرض السكري.

يمكن استخدام إمبازيميت إلى جانب أدوية أخرى لعلاج مرض السكري بما فيها الأدوية التي يتم تناولها عن طريق الفم أو عن طريق الحقن مثل الأنسولين.

بالإضافة إلى ذلك، يمكن استخدام إمبازيميت كمساعد إضافي لمبازيفلوزين وميتفورمين كأدوية إضافية لا تتناول إفراز إمبازيفلوزين وميتفورمين بشكل مستقل أثناء تناول هذا الدواء. لذا، يجب عليك معرفة ذلك مع طبيبك.

من الضروري أن تتبع نظامك الغذائي ونمط حياتك اليومي الياسية وفقاً لإرشادات الطبيب المعالج أو الصيدلي

٢. ما الذي يجب عليك معرفته قبل تناول إمبازيميت

لا تتناول إمبازيميت

إذا كنت تعاني من حساسية تجاه إمبازيفلوزين أو ميتفورمين أو أي من مكونات هذا الدواء الأخرى (المدرجة في القسم ٦).

إذا كنت تعاني من داء السكري غير المتحكم للغاية أو في سبيل العلاج، فربما سكر الدم الجاد (ارتفاع شديد في مستوى الجلوكوز في الدم)، غثيان في إسهال، فقدان الوزن السريع، حمض اللبنيك، (مرحلة “خطر الإصابة بالحمض اللبنيك”)، إسهال، والحمض الكيتوني، مرض حاد مع حساسية حيث تتراكم أحماض تسمى الأجسام الكيتونية في الدم والتي يمكن أن تكون خطيرة.

إذا كنت قد عانيت سابقاً من القيوية السكرية.

إذا كنت تعاني من قصور حاد في وظائف الكلى.

إذا كنت تعاني من التهاب حاد، قد يؤدي هذا الالتهاب الجاد إلى مشاكل في الكلى وبالتالي تصبح أكثر عرضة للإصابة بالحمض اللبنيك (مراجعة قسم “الاحتذبات والاحتياطات”).

إذا فقدت نسبة كبيرة من السوائل في جسمك (الجفاف) أو في الكلى وبالتالي تصبح أكثر عرضة للإصابة بالحمض اللبنيك (مراجعة قسم “الاحتذبات والاحتياطات”).

إذا كنت تعاني من مشاكل في الكبد.