

PATIENT INFORMATION LEAFLET

Empagliflozin Tablets (5/10/25 mg) **EMPAZ 5/10/25**

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:

1. What Empaz 5/10/25 is and what it is used for
2. What you need to know before you take Empaz 5/10/25
3. How to take Empaz 5/10/25
4. Possible side effects
5. How to store Empaz 5/10/25
6. Contents of the pack and other information

1. What Empaz 5/10/25 is and what it is used for

Empaz 5/10/25 contains an active substance empagliflozin which works by blocking a protein in the kidneys called sodium-glucose co-transporter 2 (SGLT2). SGLT2 prevents glucose from being excreted in urine by absorbing glucose into the bloodstream as blood is being filtered in the kidneys. By blocking this protein, the medicine causes glucose (blood sugar) to be removed via urine. Blood glucose levels, which are too high because of your type 2 diabetes, are thereby reduced.

- ❖ Empaz 5/10/25 is used to treat type 2 diabetes in adult patients (aged 18 years and older) that cannot be controlled by diet and exercise alone.
- ❖ Empaz 5/10/25 can be used without other medicines in patients who cannot take metformin (another diabetes medicine).
- ❖ Empaz 5/10/25 can also be used with other medicines. These may be medicines taken by mouth or insulin given by injection.

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

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

2. What you need to know before you take Empaz 5/10/25

Do not take Empaz 5/10/25

- ❖ if you are allergic to empagliflozin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Empaz 5/10/25:

- ❖ if you have "type 1 diabetes". This type usually starts when you are young and your body does not produce any insulin.
- ❖ if you have increased levels of "ketone bodies" in your urine or blood, seen in laboratory tests. This is a sign of "diabetic ketoacidosis" – a problem you can get with diabetes whose signs include rapid weight loss, feeling sick or being sick, a sweet smell to your breath, a sweet or metallic taste in your mouth or a strange odour to your urine or sweat.

- ❖ if you have serious kidney problems – your doctor may ask you to take a different medicine.
- ❖ if you 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 are 85 years old or older as you should not start taking Empaz 5/10/25.
- ❖ if you are being sick, 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 Empaz 5/10/25 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 Empaz 5/10/25 until you have recovered.

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 Empaz 5/10/25

Tell your doctor if you are taking, have recently taken or might take any other medicines.

It is important to tell your doctor:

- ❖ if you are taking a medicine used to remove water from the body (diuretic). Your doctor may ask you to stop taking Empaz 5/10/25.
- ❖ 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).

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 Empaz 5/10/25 if you are pregnant. It is unknown if Empaz 5/10/25 is harmful to the unborn child.

Do not use Empaz 5/10/25 if you are breast-feeding. It is not known if Empaz 5/10/25 passes into human breast milk.

Driving and using machines

Empaz 5/10/25 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 Empaz 5/10/25.

3. How to take Empaz 5/10/25

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

How much to take

- ❖ The starting dose of Empaz 5/10/25 is one tablet once a day. Your doctor will decide whether to increase your dose.
- ❖ Your doctor may limit your dose 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.

How to take 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.

Your doctor may prescribe Empaz 5/10/25 together with another diabetes medicine. 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 use its blood sugar better. It is important to stay on the diet and exercise program recommended by your doctor while taking Empaz 5/10/25.

If you take more Empaz 5/10/25 than you should

If you take more Empaz 5/10/25 than you should, talk to a doctor immediately or go to a hospital immediately.

If you forget to take Empaz 5/10/25

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 Empaz 5/10/25 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 Empaz 5/10/25 to make up for a forgotten dose.

If you stop taking Empaz 5/10/25

Do not stop taking Empaz 5/10/25 without first consulting your doctor. Your blood sugar levels may increase when you stop taking Empaz 5/10/25.

4. What are the possible side effects of Empaz 5/10/25

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Low blood sugar (hypoglycemia), seen very commonly (may affect more than 1 in 10 people)

If you take Empaz 5/10/25 with another medicine that can cause low blood sugar, such as a sulfonylurea 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 Empaz 5/10/25 works, but as 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 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 and fainting or loss of consciousness.

Other side effects while taking Empaz 5/10/25:

Common

- ❖ thrush or genital yeast infection
- ❖ passing more urine than usual or needing to pass urine more often
- ❖ itching

Uncommon

- ❖ straining or pain when emptying the bladder

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.

5. How to store Empaz 5/10/25

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 carton after EXP. The expiry date refers to the last day of that month. Store in a dry place at or below 30°C.

Do not use this medicine if the package is damaged or shows signs of tampering.

6. Contents of the pack and other information

The active substance is Empagliflozin.

Each film coated tablet contains:

Empagliflozin 5 mg

Colours: Iron Oxide Yellow & Titanium Dioxide

Each film coated tablet contains:

Empagliflozin 10 mg

Colours: Iron Oxide Yellow & Titanium Dioxide

Each film coated tablet contains:

Empagliflozin 25 mg

Colours: Iron Oxide Yellow & Titanium Dioxide

What Empaz 5/10/25 looks like and contents of the pack

EMPAZ 5 is 6.5 mm round, biconvex, film coated tablet with breakline on one side. It is available in PVDC blister. The pack size is 4 x 3 x 10 tablets in a printed carton.

EMPAZ 10 is 8 mm round, biconvex, film coated tablet with breakline on one side. It is available in PVDC blister. The pack size is 4 x 3 x 10 tablets in a printed carton.

EMPAZ 25 is 12.8 x 5.7 mm oval, biconvex, film coated tablet with break line on one side. It is available in PVDC blister. The pack size is 4 x 3 x 10 tablets in a printed carton.



Manufactured by :
Quest Pharmaceuticals Pvt. Ltd.
Chhata Pipara, Bara, Nepal

For further information
Quest Pharmaceuticals Pvt. Ltd.
Tripureshwar, Kathmandu
Tel. 01-4240304; Email : quest.ktm@quest.com.np,
Website : www.quest.com.np