

# PATIENT INFORMATION LEAFLET

Empagliflozin & Linagliptin Tablets  
(10 mg/5 mg & 25 mg/5 mg)

## EMPAZ L 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 L is and what it is used for
2. What you need to know before you take EMPAZ L
3. How to take EMPAZ L
4. What are the possible side effects of EMPAZ L
5. How to store EMPAZ L
6. Contents of the pack and other information

### 1. What EMPAZ L is and what it is used for

EMPAZ L contains two active substances called Empagliflozin and Linagliptin. Each belongs to a group of medicines called "oral anti-diabetics". These are medicines taken by mouth to treat Type 2 diabetes.

EMPAZ L is added to metformin and/or sulphonylurea (SU) to treat type 2 diabetes in adult patients aged 18 years and older whose diabetes cannot be controlled when treated with metformin and/or sulphonylurea in combination with empagliflozin, or when treated with metformin and/or sulphonylurea in combination with linagliptin.

EMPAZ L can also be used as an alternative to taking both Empagliflozin and Linagliptin as single tablets. To avoid overdose, do not continue taking Empagliflozin and Linagliptin tablets separately, if you are taking this medicine

### 2. What you need to know before you take EMPAZ L

#### Do not take EMPAZ L if:

If you are allergic to empagliflozin, linagliptin, any other SGLT2 inhibitor (e.g. dapagliflozin, canagliflozin), any other DPP-4 inhibitor (e.g. sitagliptin, vildagliptin), or any of the other ingredients of this medicine.

### Warnings and precautions

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

- ❖ If you have type 1 diabetes (your body does not produce any insulin), Empaz L should not be used may limit your daily dose or ask you to take a different medicine
- ❖ 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 as these symptoms could be a sign of "diabetic ketoacidosis" – a rare, but serious, sometimes life-threatening problem you can get with diabetes because of excessive levels of "ketone bodies" in your urine or blood, seen in tests.
- ❖ If you have or have had a disease of the pancreas.
- ❖ If you have serious kidney problems. Your doctor may limit your daily dose or ask you to take a different medicine
- ❖ If you have serious liver problems. Your doctor may ask you to take a different medicine.
- ❖ If you 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 or lower blood pressure
- ❖ Possible signs of dehydration: Your doctor may ask you to stop taking EMPAZ L until you recover to prevent loss of too much body fluid. Ask about ways to prevent dehydration.
- ❖ If you are 75 years old or older, you should not start taking EMPAZ L.
- ❖ If you have an increase in the proportion of red blood cells in your blood (hematocrit), seen in laboratory blood tests
- ❖ Contact your doctor if you experience any of the following during treatment with EMPAZ L:

- ❖ If you develop symptoms of acute pancreatitis, like persistent, severe stomach ache (abdominal pain).
- ❖ If you have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking EMPAZ L until you have recovered.
- ❖ If you encounter blistering of the skin, it may be a sign for a condition called bullous pemphigoid.

### Other medicines and EMPAZ L

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, you should tell your doctor if you are using the following medicines:

- ❖ Other anti-diabetic medicines, such as insulin or a sulphonylurea. Your doctor may want to lower the dose of these other medicines, to prevent your blood sugar levels from getting too low.
- ❖ Medicines used to remove water from your body (diuretics). Your doctor may ask you to stop taking EMPAZ L.
- ❖ Medicines that might have an effect on the breakdown of empagliflozin or linagliptin in your body such as rifampicin (an antibiotic used to treat tuberculosis) or certain medicines used to treat seizures (such as carbamazepine, phenobarbital or phenytoin). The effect of EMPAZ L may be reduced.
- ❖ Lithium because EMPAZ L can lower the amount of lithium in your blood

### Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. It is not known whether EMPAZ L is harmful to the unborn child. As a precautionary measure it is preferable to avoid the use of this medicine during pregnancy. It is not known whether the active substances of EMPAZ L pass into human breast milk. Do not use this medicine if you are breast-feeding. It is not known whether EMPAZ L has an effect on the fertility in humans.

### Driving and using machines

EMPAZ L has minor influence on the ability to drive and use machines.

Taking this medicine in combination with sulphonylureas or insulin, can cause your blood sugar levels to drop too low (hypoglycaemia), which may cause symptoms such as shivering, sweating and changes in vision, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you experience any of these symptoms while taking EMPAZ L.

### 3. How to take EMPAZ L

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 usual starting dose is one film coated tablet of EMPAZ L 10 mg/5 mg (10 mg empagliflozin and 5 mg linagliptin) once a day.

Your doctor will decide whether you need to increase your dose to one film-coated tablet of EMPAZ L 25 mg/5 mg (25 mg empagliflozin and 5 mg linagliptin) once a day. If you already take 25 mg empagliflozin and 5 mg linagliptin as separate tablets and you switch to EMPAZ L, you can start directly with EMPAZ L 25 mg/5 mg.

#### Renal impairment

Talk to your doctor if you have kidney problems. Your doctor may limit your dose or decide to use an alternative medicine.

#### Hepatic impairment

Talk to your doctor in case you suffer from severe hepatic impairment. EMPAZ L is not recommended and your doctor may decide to use an alternative medicine.

#### Elderly

There is very little experience in patients aged 75 years or older. Treatment with EMPAZ L should not be started in patients above the age of 75.

#### How to take EMPAZ L tablets

Swallow the tablet whole with water.

- ❖ You can take EMPAZ L 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 L together with another anti-diabetic 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 to use its blood sugar better. It is important to stay on the diet and exercise program recommended by your doctor while taking EMPAZ L.

### How long to take EMPAZL for

EMPAZL is a long-term treatment keep taking EMPAZL until your doctor tells you to stop.

### If you take more EMPAZL than you should

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

### If you forget to take EMPAZL

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 EMPAZL 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 this medicine to make up for a forgotten dose.

### If you stop taking EMPAZL

Do not stop taking this medicine without first consulting your doctor. Your blood sugar levels may increase when you stop taking EMPAZL.

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.

#### Urinary tract infection, seen commonly

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 this medicine 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.

#### Loss of body fluid (dehydration), seen uncommonly

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 EMPAZL:

Seen commonly

- ❖ genital yeast infection like thrush
- ❖ inflamed nose or throat (nasopharyngitis)
- ❖ cough
- ❖ passing more urine than usual or needing to pass urine more often
- ❖ itching
- ❖ skin rash
- ❖ increased blood enzyme amylase
- ❖ increased pancreas enzyme lipase
- ❖ thirst
- ❖ constipation

Contact a doctor or the nearest hospital straight away if you have any of the following side effects:

#### Diabetic ketoacidosis, seen rarely (may affect up to 1 in 1000 people)

These are the signs of diabetic ketoacidosis

- 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 this medicine.

Contact your doctor immediately if you notice any of the following side effects:

#### Allergic reactions, seen uncommonly (may affect up to 1 in 100 people)

This medicine may cause allergic reactions, which may be serious, including hives (urticaria) and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing (angioedema).

#### Inflammation of the pancreas (pancreatitis), seen uncommonly

This medicine may cause pancreatitis, which usually shows as persistent, severe abdominal (stomach) pain that might reach through to your back, often accompanied by feeling sick or being sick. Your doctor will need to change your treatment.

#### Low blood sugar (hypoglycaemia), seen commonly (may affect up to 1 in 10 people)

If you take EMPAZL with another medicine that can cause low blood sugar, such as sulphphonylurea or insulin, you are at risk of getting too low blood sugar (hypoglycaemia).

The signs of too 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.

### 5. How to store EMPAZL

- ❖ 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 carton and blister after EXP.
- ❖ The expiry date refers to the last day of that month.
- ❖ This medicine does not require any special storage conditions.
- ❖ 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 EMPAZL contains

The active substance is Empagliflozin and Linagliptin.

#### EMPAZL 10

Each film coated tablet contains:

Empagliflozin 10mg  
Linagliptin IP 5 mg  
Colours: Iron Oxide Red & Titanium Dioxide

#### EMPAZL 25

Each film coated tablet contains:

Empagliflozin 25 mg  
Linagliptin IP 5 mg  
Colours: Brilliant Blue Lake, Tartrazine Lake & Titanium Dioxide

#### What EMPAZL looks like and contents of the pack

EMPAZL 10 is red, round, biconvex, film coated tablets. EMPAZL 10 tablets are packed in PVDC Blister. The pack size is 4 x 3 x 10 tablets in a printed paper carton.

EMPAZL 25 is green, round, biconvex, film coated tablets with 'Q' logo scored on one side. EMPAZL 25 tablets are packed in PVDC Blister. The pack size is 4 x 3 x 10 tablets in a printed paper carton.



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