PHARMACOR EMPAGLIFLOZIN

Film-coated tablets
Empagliflozin

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Pharmacor Empagliflozin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Pharmacor Empagliflozin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp (New Zealand) and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with the medicine.

You may need to read it again.

What Pharmacor Empagliflozin is used for

Pharmacor Empagliflozin is used to lower blood sugar levels in adults and children aged 10 years and older with type 2 diabetes mellitus.

Type 2 Diabetes Mellitus

It may be used when diet plus exercise do not provide adequate blood sugar level control either:

- alone as a single medicine, or
- in combination with certain other anti-diabetic medicines such as:
  - metformin, or
  - sulfonylurea medicines such as glimepiride and glibenclamide, or
  - pioglitazone, or
  - insulin, or
  - dipeptidyl peptidase-4 inhibitor medicines such as linagliptin.

In adult patients with type 2 diabetes mellitus and cardiovascular disease, Pharmacor Empagliflozin can be used to reduce your risk of dying from your cardiovascular disease.

Type 2 diabetes mellitus is also called non-insulin-dependent diabetes mellitus or NIDDM. Type 2 diabetes develops if the body does not make enough insulin, or if the insulin that your body makes does not work as well as it should.

Insulin is a substance which helps to lower the level of sugar in your blood, especially after meals.

When the level of sugar builds up in your blood, this can cause damage to the body's cells and lead to serious problems with your heart, eyes, circulation or kidneys.

Heart failure

In heart failure, the heart does not work as well as it should. This means the heart is unable to pump enough blood to meet the body's needs. The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling. Pharmacor Empagliflozin is used to treat long-term heart failure in adult patients. Pharmacor Empagliflozin also helps to slow down worsening of kidney function in these patients with heart failure. It may be used whether or not you have type 2 diabetes mellitus.

Chronic kidney disease

Chronic kidney disease is the condition when your kidneys gradually lose their function. This means they would not be able to clean and filter your blood the way they should. Loss of kidney function can lead to serious medical problems and need for hospital care.

In adult patients Pharmacor Empagliflozin helps protect your kidneys from losing their function and can help some patients to live longer.

How Pharmacor Empagliflozin works

Pharmacor Empagliflozin contains the active ingredient, empagliflozin, which belongs to a group of medicines called SGLT2 (sodium-glucose co-transporter 2) inhibitors.

Pharmacor Empagliflozin works by blocking a protein in the kidneys called SGLT2. Pharmacor Empagliflozin removes blood sugar, which is too high because of your type 2 diabetes mellitus, via the urine. As a result, the levels of glucose in your blood are reduced.

Pharmacor Empagliflozin also reduces the amount of salt reabsorbed by your kidneys, which helps to reduce excess strain on the heart.

Pharmacor Empagliflozin may also help to protect your kidneys from further damage caused by high blood sugar levels and excess strain on the heart.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Pharmacor Empagliflozin is available only with a doctor's prescription.

Before you take JAGLIX

When you must not take it

Do not take Pharmacor Empagliflozin if you have an allergy to:

- any medicine containing empagliflozin (the active ingredient in Pharmacor Empagliflozin)
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Pharmacor Empagliflozin if you have severe problems with your kidneys.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy**.**

Do not breastfeed if you are taking this medicine.

It is not known if the active ingredient in Pharmacor Empagliflozin passes into human breast milk and there is a possibility that your baby may be affected.

Pharmacor Empagliflozin can be used in children aged 10 years and older for the treatment of type 2 diabetes mellitus.

Safety and effectiveness in children younger than 10 years has not been established.

Pharmacor Empagliflozin is not recommended for children and adolescents under 18 years of age for the treatment of heart failure or chronic kidney disease, as safety and efficacy in this age group has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- type 1 diabetes, a condition where your body does not produce insulin
- diabetic ketoacidosis, a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include: rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, 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.
- kidney problems
- galactosaemia, a rare hereditary condition of galactose intolerance
- frequent genital or urinary tract infections (infections of the bladder, kidney, or tubes that carry urine)

- illnesses that will make you dehydrated (e.g. diarrhoea or a severe infection)

- increased urine loss which may affect the fluid balance in your body.

Tell your doctor if you have heart problems, a history of low blood pressure or are 75 years of age or older.

Increased passing of urine due to the medicine may affect fluid balance in your body and increase your risk of dehydration.

If you have not told your doctor about any of the above, tell him/her before you start taking Pharmacor Empagliflozin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Pharmacor Empagliflozin may interfere with each other. These include medicines used to treat high blood pressure known as water pills (diuretics).

Pharmacor Empagliflozin may lower the amount of lithium in your blood (medicine used to treat and prevent mood disorders). Your doctor will need to do more frequent monitoring to check on the amount of lithium in your blood.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Pharmacor Empagliflozin

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Type 2 Diabetes Mellitus

The recommended dose is one 10 mg tablet once a day.

Your doctor may increase your dose to 25 mg once a day if your blood glucose levels remain high after starting treatment on 10 mg.

Your doctor will prescribe Pharmacor Empagliflozin alone, or in combination with another anti-diabetic medicine if that medicine alone is not sufficient to control your blood sugar level.

Heart Failure

The recommended dose is one 10 mg tablet once a day.

Chronic kidney disease

The recommended dose is one 10 mg tablet once a day.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but will not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 764 766) for advice or go to Emergency if you think that you or anyone else may have taken too much Pharmacor Empagliflozin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Pharmacor Empagliflozin

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Pharmacor Empagliflozin.

Tell any other doctors and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

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 Pharmacor Empagliflozin.

Make sure you check your blood glucose regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

Check your feet regularly and see your doctor if you notice any problems. Follow any other advice regarding foot care given by your doctor.

If you are going to have a procedure (surgery), tell the doctor that you are taking this medicine.

Your doctor may decide to temporarily stop your treatment with Pharmacor Empagliflozin.

Your doctor will tell you when to stop taking Pharmacor Empagliflozin and when to start taking it again.

Things you must not do

Do not take Pharmacor Empagliflozin to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Pharmacor Empagliflozin affects you.

When taken with other anti-diabetic medicines, such as sulfonylurea or insulin, your risk of getting low blood sugar is higher.

This may cause dizziness, light-headedness, tiredness, drowsiness in some people. Low blood glucose levels may also slow your reaction time and affect your ability to drive or operate machinery.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when doing any of the following things, which may increase the risk of your blood glucose becoming too low:

- drinking alcohol
- not eating enough
- doing unexpected or vigorous exercise.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Pharmacor Empagliflozin.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- genital burning, redness, pain and discharge which may be signs of a genital yeast infection
- passing more urine than normal
- itching
- thirst
- constipation.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the symptoms of low blood sugar such as:

- sweating
- weakness
- hunger
- dizziness
- trembling
- headache
- flushing or paleness
- numbness
- a fast pounding heartbeat.

Low blood sugar may occur in patients who already take another medication to treat diabetes, such as a sulfonylurea or insulin. The dose of your sulfonylurea or insulin medicine may need to be reduced while taking Pharmacor Empagliflozin.

Tell your doctor as soon as possible if you notice any of the following:

- burning sensation when passing urine
- urine that appears cloudy
- pain in the pelvis, or mid-back pain
- straining or pain when passing urine
- unusual thirst
- light-headedness, or dizziness upon standing
- fainting or loss of consciousness.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor immediately if you experience pain or tenderness, itching, swelling in the genital or back passage area, fever or are generally feeling unwell.

These may be symptoms of a serious and life-threatening infection called Fournier's gangrene. Your doctor may tell you to stop taking Pharmacor Empagliflozin.

Tell your doctor immediately or go to Emergency if you notice any of the following:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of itchy or raised skin rash, hives or nettle rash.

Tell your doctor immediately or go to Emergency if you notice any of the symptoms of diabetic ketoacidosis such as:

- 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.

In rare cases, empagliflozin, the active substance in Pharmacor Empagliflozin, can cause a serious side effect called diabetic ketoacidosis. 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After using Pharmacor Empagliflozin

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store Pharmacor Empagliflozin or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Pharmacor Empagliflozin is the brand name of your medicine.

Pharmacor Empagliflozin is available in two strengths:

- PHARMACOR EMPAGLIFLOZIN 10 mg are Pale yellow, round shaped, biconvex film-coated tablets, debossed with "E10" on one side and plain on other side.

- PHARMACOR EMPAGLIFLOZIN 25 mg are Pale yellow, oval shaped, biconvex film-coated tablets, debossed with “E25” on one side and plain on other side.

Pharmacor Empagliflozin tablets come in a Al-Al Desiccant blister pack of 10 (sample) & 30 tablets and HDPE bottle of 30, 90 & 1000 tablets.

Ingredients

Active ingredient:
PHARMACOR EMPAGLIFLOZIN 10 mg tablets contain 10 mg of Empagliflozin.

PHARMACOR EMPAGLIFLOZIN 25 mg tablets contain 25 mg of Empagliflozin.

Inactive ingredients:

- Microcrystalline Cellulose
- Maize Starch
- Croscarmellose Sodium
- Hypromellose
- Colloidal Silicon Dioxide
- Magnesium Stearate

Tablet coating (Opadry 02B38190 Yellow):

- Hypromellose E464
- Titanium Dioxide E171
- Purified Talc E553b
- Macrogol E1521
- Iron oxide yellow E172

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

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Australian Register Number:

- 322380 - PHARMACOR EMPAGLIFLOZIN empagliflozin 10 mg tablet bottle pack
- 322382 - PHARMACOR EMPAGLIFLOZIN empagliflozin 10 mg tablet blister pack
- 322385 - PHARMACOR EMPAGLIFLOZIN empagliflozin 25 mg tablet bottle pack
- 322384 - PHARMACOR EMPAGLIFLOZIN empagliflozin 25 mg tablet blister pack

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