What is Jardiance in this leaflet

1. What is this medicine used for
2. Before you take Jardiance
3. How to take Jardiance
4. Possible side effects
5. While you are taking Jardiance
6. Contents of the pack and other information

Jardiance is a tablet containing the active substance empagliflozin, which works by blocking a protein to reduce glucose levels. Taking empagliflozin as part of a larger treatment plan, which may include diet, exercise, and other diabetes medicine, can help lower blood sugar levels in your body and help you control your diabetes better.

Your doctor has prescribed this medicine to help lower your blood sugar. Jardiance is used to treat type 2 diabetes in adult patients aged 18 years and older that cannot be controlled by diet and exercise alone.

How to take Jardiance

Do not take:

- If you are allergic to empagliflozin or any of the other ingredients of this medicine (listed in section 6).

- If you have type 1 diabetes.

- If you have had a heart attack or had surgery called coronary angioplasty or percutaneous transluminal coronary angioplasty (PTCA).

The following information explains how to use Jardiance. Your doctor will have told you to take Jardiance with or without food.

Take one Jardiance tablet each day. You may take the tablet at any time of day, but it is best to take it at the same time each day. If you forget to take the tablet:

- You should take the dose you have missed as soon as you remember. Do not take two tablets at the same time.

- If you do not remember when you took the last tablet, you should take the next tablet at your regular time.

Take the tablet whole, do not cut or break it. If you need to, you can crush the tablet and take it with food. Jardiance is to be swallowed whole. It is not to be used for children.

How much to take

The starting dose of Jardiance is 30 mg tablet once a day. Your doctor will decide whether to increase your dose to 25 mg once a day or continue with the original dose depending on your blood sugar levels. The maximum single dose is 25 mg once a day.

Other medicines and Jardiance

Tell your doctor if you are taking any other medicines, including herbal medicines and vitamins, that may affect your blood sugar levels, kidney function, or heart failure.

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Tell your doctor if you are taking any other medicines, including herbal medicines and vitamins, that may affect your blood sugar levels, kidney function, or heart failure.

- If you have high blood pressure, you should also tell your doctor and pharmacist that you are taking Jardiance.

- If you have heart disease, you should also tell your doctor and pharmacist that you are taking Jardiance.

- If you have liver disease, you should also tell your doctor and pharmacist that you are taking Jardiance.

- If you have kidney disease, you should also tell your doctor and pharmacist that you are taking Jardiance.

- If you are taking other medicines that lower the amount of sodium in your blood such as renin inhibitors (e.g. aliskiren or eplerenone) or spironolactone, you should also tell your doctor and pharmacist that you are taking Jardiance.

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Package leaflet: Information for the patient

Jardiance 10 mg film-coated tablets
25 mg film-coated tablets

emphar

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of this leaflet for how to report side effects.

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 this leaflet for?

1. Why is Jardiance used and what is it used for?

Jardiance is used to treat type 2 diabetes in adult patients aged 18 years and older that cannot be controlled by diet and exercise alone.

Your doctor has prescribed this medicine to help lower your blood sugar.

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Your doctor has prescribed this medicine to help lower your blood sugar.

• Jardiance can be used with other medicines in patients who cannot take insulin.

• Jardiance can be used with other medicines. These may be medicine 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.

2. How to take Jardiance

• Jardiance can be used with other medicines in patients who cannot take insulin.

• Jardiance can be used with other medicines. These may be medicine 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.

Take Jardiance regular tablet with water once a day. This will help you to remember to take Jardiance.

Your doctor may prescribe Jardiance together with other medicines to help achieve the best results for your health.

3. How to take Jardiance

• 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 “bad” lipids in your urine or blood, seen in laboratory tests. This is a sign of “diabetic nephropathy”.

• If you have type 2 diabetes whose urine includes rapid weight loss, feeling sick or having sweats, a sweet smell to your breath, a sweet or metallic taste in your mouth or a strange odor to your urine or sweat.

• If you have serious kidney problems – your doctor may ask you to take a different medicine.

• If you get more than 2 doses of insulin, or if you are taking insulin in slow-release or long-acting form. This can affect your blood sugar levels.

• If you have a history of low blood sugar (known as hypoglycaemia) and you are at risk, your doctor or pharmacist may advise you to take Jardiance instead of your previous medicine.

4. Possible side effects

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 (hypoglycaemia), seen commonly (may affect more than 1 in 10 people)

You may have further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Driving and using machines

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

So, you must avoid driving or using any tools or machines. If you feel dizzy while taking Jardiance

Jardiance is not recommended for children and adolescents under 18 years, because it has not been tested in these age groups.

• Jardiance is not recommended for children and adolescents under 3 years, because it has not been tested in this age group.

• If you have a history of low blood sugar (known as hypoglycaemia) and you are at risk, your doctor or pharmacist may advise you to take Jardiance instead of your previous medicine.

• If you get more than 2 doses of insulin, or if you are taking insulin in slow-release or long-acting form. This can affect your blood sugar levels.

5. Interaction with other medicines and foods

• When you stop taking Jardiance until you recover to prevent loss of too much blood.

• If you have a serious infection of the kidney or the urinary tract. Contact your doctor.

• You can take the tablet at any time of the day.

• If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

• You must not take Jardiance:

• If you have type 1 diabetes. This is a type of diabetes whose urine may include diabetes in your urine or blood, seen in laboratory tests. This is a sign of “diabetic nephropathy”.

• If you have type 2 diabetes whose urine includes rapid weight loss, feeling sick or having sweats, a sweet smell to your breath, a sweet or metallic taste in your mouth or a strange odor to your urine or sweat.

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• If you have serious kidney problems – your doctor may ask you to take a different medicine.

• If you get more than 2 doses of insulin, or if you are taking insulin in slow-release or long-acting form. This can affect your blood sugar levels.

6. What to do if you take too much Jardiance

• You can take a double dose of Jardiance to make up for a forgotten dose.

• Do not take a double dose of Jardiance to make up for a forgotten dose.

7. How to dispose of Jardiance

• If you stop taking Jardiance, you should continue your diet and exercise plan as told by your doctor or pharmacist.

• You can take a double dose of Jardiance to make up for a forgotten dose.

• Do not take a double dose of Jardiance to make up for a forgotten dose.

8. How to store Jardiance

• Do not take a double dose of Jardiance to make up for a forgotten dose.

• Do not take a double dose of Jardiance to make up for a forgotten dose.

9. How to control side effects

• Do not take a double dose of Jardiance to make up for a forgotten dose.

• Do not take a double dose of Jardiance to make up for a forgotten dose.

10. How to get medical advice

• Do not take a double dose of Jardiance to make up for a forgotten dose.

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11. Further information

• Do not take a double dose of Jardiance to make up for a forgotten dose.

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The active substance is empagliflozin.

What Jardiance contains

6. Contents of the pack and other information

What Jardiance contains

• The active substance is empagliflozin. Each tablet contains 10 mg or 25 mg empagliflozin.

• The other ingredients are:
  - tablet core: lactose monohydrate (lactose), colloidal silicon dioxide, magnesium stearate,
  - film-coating: hypromellose, titanium dioxide (E171), talc, macrogol (400), iron oxides yellow (E172)

What Jardiance looks like and contents of the pack

Jardiance 25 mg film-coated tablets are oval, pale yellow and biconvex. They have “S25” on one side and the Boehringer Ingelheim logo on the other side. The tablet is 11 mm long and has a width of 5.6 mm.

Jardiance 10 mg film-coated tablets are round, pale yellow and biconvex. They have “S10” on one side and the Boehringer Ingelheim logo on the other side. The tablets are 11 mm in diameter.
What Jardiance contains

The active substance is empagliflozin.

The other ingredients are:

- lactose, magnesium stearate, colloidal anhydrous silica, titanium dioxide (E171), talc, macrogol (400), iron oxide yellow (E172)

What is Jardiance for?

Jardiance is indicated for the treatment of type 2 diabetes mellitus (T2DM) in combination with diet and exercise in adults with T2DM who have inadequately responded to metformin alone or in combination with a sulfonylurea, a dipeptidyl peptidase-4 inhibitor, a thiazolidinedione, or a glucagon-like peptide-1 receptor agonist. It is also indicated for the treatment of adults with T2DM as monotherapy or in combination with another oral antidiabetic agent.

What are the properties of Jardiance?

Jardiance is a once-daily oral medicine that reduces blood glucose levels by increasing the amount of glucose that the body releases into the urine. It is available in two strengths: 10 mg and 25 mg.

How do you take Jardiance?

Jardiance is taken by mouth, once daily, with or without food. The tablets are round, 9.1 mm in diameter, with "S10" on one side and the Boehringer Ingelheim logo on the other side. The tablets have a width of 5.6 mm. Jardiance is available in PVC/aluminium perforated unit dose blisters. The pack sizes are 1 x 1, 1 x 4, 1 x 8, 1 x 30, 1 x 60, 1 x 75, 1 x 100, and 1 x 200 film-coated tablets.

Not all pack sizes may be marketed in your country.

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