

# JARDIANCE DUO®

Film-coated tablets

Empagliflozin/Metformin (5mg/500mg, 12.5mg/500mg, 12.5mg/850mg & 12.5mg/1000mg)

## What is in this leaflet

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11. Date of revision
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### 1. What Jardiance Duo is used for

Jardiance Duo is used along with diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus

- when treatment with both empagliflozin and metformin is appropriate
- inadequately controlled with metformin or empagliflozin alone
- inadequately controlled with empagliflozin or metformin in combination with other glucose-lowering products including insulin
- already treated with empagliflozin and metformin co-administered as separate tablets

Jardiance Duo is used along with diet and exercise to improve blood sugar control in children with type 2 diabetes mellitus

- when treatment with both empagliflozin and metformin is appropriate
- inadequately controlled with metformin alone or in combination with insulin
- already treated with empagliflozin and metformin co-administered as separate tablets

Jardiance Duo is used to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established heart (cardiovascular) disease.

## 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 level of 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.

### 2. How Jardiance Duo works

Jardiance Duo is a diabetes medicine that contains two active substances called empagliflozin and metformin.

- Empagliflozin works by blocking a protein in the kidneys called sodium glucose co-transporter 2 (SGLT2). SGLT2 prevents glucose (blood sugar) from being lost in urine by absorbing glucose back into the bloodstream as blood is being filtered in the kidneys. By blocking this protein, the medicine causes blood sugar, sodium (salt) and water to be removed via the urine. Blood sugar levels, which are too high because of your type 2 diabetes, are thereby reduced.
- Metformin works in a different way to lower blood sugar levels, mainly by blocking glucose production in the liver.

### 3. Before you use Jardiance Duo

#### When you must not use it

- if you are allergic to empagliflozin, metformin or any of the other ingredients of this medicine (listed in section *Ingredient*);
- if you have severely reduced kidney function;
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see section '*Risk of lactic acidosis*' below) or ketoacidosis. Ketoacidosis is a condition 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 a severe infection such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see section '*Before you start to use it*');;

- if you have lost a lot of water from your body (dehydration), e.g. due to long-lasting or severe diarrhoea, or if you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see section '*Before you start to use it*');;
- if you are treated for acute heart failure 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 '*Before you start to use it*');;
- if you have problems with your liver;
- if you drink alcohol to excess, either every day or only from time to time (see section '*Jardiance Duo with alcohol*').

#### Before you start to use it

Talk to your doctor, pharmacist or nurse before taking Jardiance Duo:

- about what you can do to prevent dehydration
- if you have "type 1 diabetes" – this type usually starts when you are young and your body does not produce any insulin;
- 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 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 diabetes 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 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. Possible signs are listed in section ‘Side effects’, dehydration;
- if you have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking Jardiance Duo until you have recovered;
- 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.

### **Risk of lactic acidosis**

Jardiance Duo 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 acute severe heart diseases). If any of the above apply to you, talk to your doctor for further instructions.

### **Stop taking Jardiance Duo for a short time if you have a condition that may 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 instruction.

### **Stop taking Jardiance Duo and contact your doctor or the nearest hospital immediately if you experience some 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 hospital.

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

During treatment with Jardiance Duo, 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.

### **Vitamin B12**

Metformin may lower vitamin B12 levels. Periodic vitamin B12 monitoring is necessary. Metformin therapy should be continued as long as it is tolerated and not contra-indicated and appropriate corrective treatment for vitamin B12 deficiency in line with current guidelines.

### **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**

Jardiance Duo can be used in children aged 10 years and older for the treatment of type 2 diabetes. No data are available in children below 10 years of age.

### Taking other medicines

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 Jardiance Duo before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Jardiance Duo.

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 your doctor may need to adjust the dosage of Jardiance Duo. It is especially important to mention the following:

- medicines which increase urine production (diuretic), as Jardiance Duo may increase the risk of losing too much fluid. Your doctor may ask you to stop taking Jardiance Duo. Possible signs of losing too much fluid from your body are listed in section ‘Side effects’.
- other medicines that lower the amount of sugar in your blood such as insulin or a “sulfonylurea” 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 which 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, crizotinib, 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.
- Medicine use to treat pain and inflammation (NSAID and COX-2-

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| <p>inhibitors, such as ibuprofen and celecoxib)</p> <ul style="list-style-type: none"> <li>• Certain medicines for the treatment of high blood pressure (ACE inhibitor and angiotensin II receptor antagonists)</li> <li>• medicines that contain alcohol (see section ‘Jardiance Duo with alcohol’).</li> <li>• iodinated contrast agents (medicines used during an X-ray, see section ‘Before you start to use it’).</li> <li>• if you are taking lithium because Jardiance Duo can lower the amount of lithium in your blood.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p><u>How long to use it</u></p> <p>Continue taking Jardiance Duo for as long as your doctor recommends.</p> <p><u>If you forget to use it</u></p> <p>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.</p> <p><u>If you use too much (overdose)</u></p> <p>If you take more Jardiance Duo tablets than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific such as feeling or being very sick, vomiting, stomachache with muscle cramps, a general feeling of not being well with severe tiredness and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat. <b>If this happens to you, you may need immediate hospital treatment, as lactic acidosis can lead to coma. Stop taking this medicine immediately and contact your doctor or the nearest hospital straight away (see section ‘Before you use Jardiance Duo’). Take the medicine pack with you.</b></p> | <p>sleepiness, frequent urination and fruity-smelling breath occur.</p> <p><u>Things you must not do</u></p> <p>Avoid consumption of alcohol and medicine containing alcohol while taking Jardiance Duo.</p> <p>Do not stop taking Jardiance Duo without first consulting your doctor. Your blood sugar levels may increase when you stop taking Jardiance Duo.</p> <p>Do not take any new medicines without consulting your doctor.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <p><b>4. How to use Jardiance Duo</b></p> <p>Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.</p> <p><u>How much to use</u></p> <p>The dose of Jardiance Duo 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.</p> <p>The recommended dose is one tablet twice daily. Your doctor will normally start Jardiance Duo treatment by prescribing the strength of tablet that supplies the same dose of metformin you are already taking (500mg, 850mg or 1000mg twice a day), and the lowest dose of empagliflozin (5mg twice a day). If you are already taking both medicines separately, your doctor will start the treatment with tablets of Jardiance Duo that will supply the same amount of both. If you have reduced kidney function, your doctor may prescribe a lower dose.</p> <p><u>Taking this medicine</u></p> <ul style="list-style-type: none"> <li>• Swallow the tablet whole in water.</li> <li>• Take the tablets with meals to lower your chance of an upset stomach.</li> <li>• Take the tablet twice daily by mouth.</li> </ul> <p><u>When to use it</u></p> <p>Use as directed by your doctor or pharmacist.</p> | <p><b>5. While you are using it</b></p> <p><u>Things you must do</u></p> <p>Your doctor may prescribe Jardiance Duo 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.</p> <p>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 Jardiance Duo.</p> <p>Seek <b>immediate</b> medical attention when symptoms such as nausea, vomiting, decreased appetite, abdominal pain, excessive thirst, difficulty in breathing, confusion, unusual fatigue or</p>                                                                                                                                                                                                                                                                                                                                                                              | <p>Do not give Jardiance Duo to anyone else, even if they have the same symptoms or conditions as you.</p> <p><u>Things to be careful of</u></p> <p><b>Jardiance Duo with alcohol</b><br/>Avoid excessive alcohol intake while taking Jardiance Duo since this may increase the risk of lactic acidosis (see section ‘Risk of lactic acidosis’).</p> <p><b>Pregnancy and breast-feeding</b><br/>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.</p> <p>Do not take Jardiance Duo if you are pregnant. It is unknown if this medicine is harmful to the unborn child.</p> <p>Metformin passes into human milk in small amounts. It is not known whether empagliflozin passes into human breast milk. Do not take Jardiance Duo if you are breast-feeding.</p> <p><b>Driving and using machines</b><br/>Jardiance Duo has minor influence on the ability to drive and use machines. Taking this medicine in combination with medicines called sulfonylureas 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</p> |

or machines if you feel dizzy while taking Jardiance Duo.

## 6. 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:**

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

Jardiance Duo may cause a very rare but very serious side effect called lactic acidosis (see section ‘Before you start to use it’). If this happens, you must **stop taking Jardiance Duo 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)**

These are the signs of diabetic ketoacidosis (see section ‘Before you start to use it’):

- Increased level 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 sugar level. Your doctor may decide to temporarily or permanently stop your treatment with Jardiance Duo.

**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 Jardiance Duo with other medicine that can cause low blood sugar, such as sulfonylurea 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 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 appear 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 Jardiance Duo works, but 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
- light-headedness or dizziness upon standing
- fainting or loss of consciousness

### **Other side effect while taking Jardiance Duo:**

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 blister
- changes the way things taste
- thirst

- blood tests may show changes in blood fat (cholesterol) levels in your blood
- constipation
- decreased vitamin B12 levels in the blood

Uncommon:

- hives
- straining or pain when emptying the bladder
- blood tests may show changes related to kidney function (creatinine or urea)
- blood test may show increase the amount of red blood cells in your blood (haematocrit)

Very rare:

- abnormalities in liver function tests, inflammation of the liver (hepatitis)
- redness of the skin (erythema)

Not known:

- severe allergic reaction (may include swelling of the face, lips, mouth, tongue, or throat that may lead to difficulty breathing or swallowing)
- 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 suspected adverse reactions

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5490, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## 7. Storage and Disposal of Jardiance Duo

### Storage

Keep this medicine out of the reach and sight of children.  
Store below 30°C.

### Disposal

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 to protect the environment.

**8. Product Description**What it looks like

Alu/ PVC/PCTFE perforated unit dose blisters.

Pack sizes of 1 x 10's, 3 x 10's and 6 x 10's film-coated tablets.

Not all pack sizes may be marketed.

- 5 mg/ 500 mg: Orange yellow, oval, biconvex film-coated tablets. One side debossed with Boehringer Ingelheim company symbol and "S5", the other side is debossed with "500"
- 12.5 mg/ 500 mg: Pale brownish purple, oval, biconvex film-coated tablets. One side debossed with Boehringer Ingelheim company symbol and "S12", the other side is debossed with "500"
- 12.5 mg/ 850 mg: Pinkish white, oval, biconvex film-coated tablets. One side debossed with Boehringer Ingelheim company symbol and "S12", the other side is debossed with "850"
- 12.5 mg/ 1000 mg: Dark brownish purple, oval, biconvex film-coated tablets. One side debossed with Boehringer Ingelheim company symbol and "S12", the other side is debossed with "1000"

Ingredients

- Active ingredient:  
Empagliflozin and metformin.
- Inactive ingredients:  
Tablet core  
Maize starch, copovidone, colloidal anhydrous silica, magnesium stearate.

Film coating

5 mg/ 500 mg: Opadry® Yellow (02B220011) [hypromellose 2910, macrogol 400, titanium dioxide (E171), yellow iron oxide (E172), talc].

12.5 mg/ 500 mg: Opadry® Pink (02B240004) [hypromellose 2910, macrogol 400, titanium dioxide (E171), black iron oxide (E172), red iron oxide (E172), talc].

12.5 mg/ 850 mg: Opadry® Pink (02B240006) [hypromellose 2910, macrogol 400, titanium dioxide (E171), black iron oxide (E172), red iron oxide (E172), talc].

12.5 mg/ 1000 mg: Opadry® Purple (02B200006) [hypromellose 2910, macrogol 400, titanium dioxide (E171), black iron oxide (E172), red iron oxide (E172), talc].

MAL number:

5 mg/ 500 mg: MAL18016142AZ  
12.5 mg/ 500 mg: MAL18016056AZ  
12.5 mg/ 850 mg: MAL18016146AZ  
12.5 mg/ 1000mg: MAL18016148AZ

**9. Manufacturer**

Boehringer Ingelheim Hellas Single Member S.A.  
5th km Paiania-Markopoulo  
Koropi Attiki  
19441  
Greece

**10. Product Registration Holder**

Boehringer Ingelheim (Malaysia) Sdn. Bhd.  
Level 23A, Mercu Aspire,  
No. 3, Jalan Bangsar, KL Eco City,  
59200 Kuala Lumpur, Malaysia.

**11. Date of revision**

25/08/2025

**12. Serial number**

NPRA (R1/6) 05122024/227