

**Empagliflozin and Metformin Hydrochloride Extended Release Tablets 5 mg/ 1000 mg**

**MODULE 1: ADMINISTRATIVE INFORMATION AND PRESCRIBED INFORMATION**

**1.6.3 Patient information leaflet (PIL)**

- Enclosed

## **Package leaflet: Information for the user**

### **Empagliflozin and metformin hydrochloride extended-release tablets**

**(5 mg/1000 mg, 10 mg/1000 mg, 12.5 mg/1000 mg and 25 mg/ 1000 mg)**

**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. Do not pass it on to others. It may harm them, even if their symptoms 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. See section 4.

#### **What is in this leaflet:**

1. What Empagliflozin and metformin hydrochloride extended-release tablets are and what they are used for
2. What you need to know before you use Empagliflozin and metformin hydrochloride extended-release tablets
3. How to use Empagliflozin and metformin hydrochloride extended-release tablets
4. Possible side effects
5. How to store Empagliflozin and metformin hydrochloride extended-release tablets
6. Contents of the pack and other information

#### **1. What Empagliflozin and metformin hydrochloride extended-release tablets are and what they are used for**

- Empagliflozin and metformin hydrochloride extended-release tablets is a prescription medicine that contains 2 prescription diabetes medicines, empagliflozin and metformin. Empagliflozin and metformin hydrochloride extended-release tablets can be used:
  - along with diet and exercise to improve blood sugar in adults with type 2 diabetes,
  - in adults with type 2 diabetes who have known cardiovascular disease when both empagliflozin and metformin is appropriate and empagliflozin is needed to reduce the risk of cardiovascular death.
- Empagliflozin and metformin hydrochloride extended-release tablets are not for people with type 1 diabetes.
- Empagliflozin and metformin hydrochloride extended-release tablets are not for people with diabetic ketoacidosis (increased ketones in the blood or urine).
- It is not known if Empagliflozin and metformin hydrochloride extended-release tablets are safe and effective in children under 18 years of age.

#### **2. What you need to know before you use Empagliflozin and metformin hydrochloride extended-release tablets**

## **Do not take Empagliflozin and metformin hydrochloride extended-release tablets**

Do not take Empagliflozin and metformin hydrochloride extended-release tablets if you:

- have moderate to severe kidney problems or are on dialysis
- have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine)
- are allergic to empagliflozin, metformin, or any of the ingredients in Empagliflozin and metformin hydrochloride extended-release tablets. See the end of this leaflet for a list of ingredients in Empagliflozin and metformin hydrochloride extended-release tablets.

## **What is the most important information I should know about Empagliflozin and metformin hydrochloride extended-release tablets?**

Serious side effects can happen in people taking Empagliflozin and metformin hydrochloride extended-release tablets, including:

**Lactic Acidosis. Metformin, one of the medicines in Empagliflozin and metformin hydrochloride extended-release tablets can cause a rare but serious condition called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital.**

Call your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you feel sleepy or drowsy
- you have stomach pains, nausea or vomiting

Most people who have had lactic acidosis with metformin have other things that, combined with metformin, led to the lactic acidosis. Tell your doctor if you have any of the following, because you have a higher chance for getting lactic acidosis with Empagliflozin and metformin hydrochloride extended-release tablets if you:

- have moderate to severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye.
- have liver problems
- drink alcohol very often, or drink a lot of alcohol in the short-term (“binge” drinking)
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids.
- have surgery
- have a heart attack, severe infection, or stroke

The best way to keep from having a problem with lactic acidosis from metformin is to tell your doctor if you have any of the problems in the list above. Your doctor may decide to stop your Empagliflozin and metformin hydrochloride extended-release tablets for a while if you have any of these things. Empagliflozin and metformin hydrochloride extended-release tablets can

have other serious side effects. See *“What are the possible side effects of Empagliflozin and metformin hydrochloride extended-release tablets?”*

## **Warnings and precautions**

**Before taking Empagliflozin and metformin hydrochloride extended-release tablets, tell your healthcare provider about all of your medical conditions, including if you:**

- have moderate to severe kidney problems
- have liver problems
- have a history of urinary tract infection or problems with urination
- have heart problems, including congestive heart failure
- are going to have surgery
- are eating less due to illness, surgery, or a change in your diet
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas
- drink alcohol very often, or drink a lot of alcohol in the short term (“binge” drinking)
- are going to get an injection of dye or contrast agents for an x-ray procedure. Empagliflozin and metformin hydrochloride extended-release tablets may need to be stopped for a short time. Talk to your doctor about when you should stop Empagliflozin and metformin hydrochloride extended-release tablets and when you should start Empagliflozin and metformin hydrochloride extended-release tablets again. See *“What is the most important information I should know about Empagliflozin and metformin hydrochloride extended-release tablets?”*
- have type 1 diabetes. Empagliflozin and metformin hydrochloride extended-release tablets should not be used to treat people with type 1 diabetes.
- have any other medical conditions
- are pregnant or plan to become pregnant.
- are a premenopausal woman (before the “change of life”), who does not have periods regularly or at all.
- are breastfeeding or plan to breastfeed.

## **Other medicines and Empagliflozin and metformin hydrochloride extended-release tablets**

Tell your healthcare provider about all the medicines you take, including prescription or over-the-counter medicines, vitamins, or herbal supplements.

## **Empagliflozin and metformin hydrochloride extended-release tablets with food and drink**

Avoid drinking alcohol very often, or drinking a lot of alcohol in a short period of time (“binge” drinking). It can increase your chances of getting serious side effects.

## **Pregnancy, breast-feeding and fertility**

**Before taking Empagliflozin and metformin hydrochloride extended-release tablets, tell your healthcare provider about all of your medical conditions, including if you:**

- are pregnant or plan to become pregnant. Empagliflozin and metformin hydrochloride extended-release tablets may harm your unborn baby. If you become pregnant while taking

Empagliflozin and metformin hydrochloride extended-release tablets, tell your doctor as soon as possible. Talk with your doctor about the best way to control your blood sugar while you are pregnant.

- are a premenopausal woman (before the “change of life”), who does not have periods regularly or at all. Talk to your doctor about birth control choices while taking Empagliflozin and metformin hydrochloride extended-release tablets if you are not planning to become pregnant since Empagliflozin and metformin hydrochloride extended-release tablets may increase your chance of becoming pregnant. Tell your doctor right away if you become pregnant while taking Empagliflozin and metformin hydrochloride extended-release tablets.
- are breastfeeding or plan to breastfeed. Empagliflozin and metformin hydrochloride extended-release tablets may pass into your breast milk and may harm your baby. Talk with your doctor about the best way to feed your baby if you are taking Empagliflozin and metformin hydrochloride extended-release tablets. Do not breastfeed while taking Empagliflozin and metformin hydrochloride extended-release tablets.

### **3. How to take Empagliflozin and metformin hydrochloride extended-release tablets**

- Take Empagliflozin and metformin hydrochloride extended-release tablets exactly as your doctor tells you to take them.
- Take Empagliflozin and metformin hydrochloride extended-release tablets by mouth 1 time each day with a meal in the morning. Taking Empagliflozin and metformin hydrochloride extended-release tablets with a meal may lower your chance of having an upset stomach.
- Take Empagliflozin and metformin hydrochloride extended-release tablets whole. Do not break, cut, crush, dissolve, or chew Empagliflozin and metformin hydrochloride extended-release tablets before swallowing. If you cannot swallow Empagliflozin and metformin hydrochloride extended-release tablets whole, tell your doctor.
- You may see something that looks like the Empagliflozin and metformin hydrochloride extended-release tablet in your stool (bowel movement). If you see tablets in your stool talk to your doctor.
- Your doctor will tell you how much Empagliflozin and metformin hydrochloride extended-release tablets to take and when to take them.
- Your doctor may change your dose if needed.
- Your doctor may tell you to take Empagliflozin and metformin hydrochloride extended-release tablets along with other diabetes medicines. Low blood sugar can happen more often when Empagliflozin and metformin hydrochloride extended-release tablets is taken with certain other diabetes medicines. See “*Possible side effects?*”
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine that you need may change. Tell your doctor right away if you have any of these conditions and follow your doctor’s instructions.
- Check your blood sugar as your doctor tells you to.
- When taking Empagliflozin and metformin hydrochloride extended-release tablets, you may have sugar in your urine, which will show up on a urine test.
- Stay on your prescribed diet and exercise program while taking Empagliflozin and metformin hydrochloride extended-release tablets.
- Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and complications of diabetes.

- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with Empagliflozin and metformin hydrochloride extended-release tablets.
- Your doctor may do certain blood tests before you start Empagliflozin and metformin hydrochloride extended-release tablets and during treatment.

### **If you take more Empagliflozin and metformin hydrochloride extended-release tablets than you should**

If you take too much Empagliflozin and metformin hydrochloride extended-release tablets, call your doctor or go to the nearest hospital emergency room right away.

### **If you forget to take Empagliflozin and metformin hydrochloride extended-release tablets**

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 two doses of Empagliflozin and metformin hydrochloride extended-release tablets at the same time. Talk with your doctor if you have questions about a missed dose.

### **If you stop taking Empagliflozin and metformin hydrochloride extended-release tablets**

Do not stop taking Empagliflozin and metformin hydrochloride extended-release tablets without talking to your doctor.

## **4. Possible side effects**

### **Empagliflozin and metformin hydrochloride extended-release tablets may cause serious side effects, including:**

- See *“What is the most important information I should know about Empagliflozin and metformin hydrochloride extended-release tablets?”*
- **Dehydration.** Empagliflozin and metformin hydrochloride extended-release tablets can cause some people to have dehydration (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, light-headed, or weak, especially when you stand up (orthostatic hypotension). You may be at higher risk of dehydration if you:
  - have low blood pressure
  - are on low sodium (salt) diet
  - have kidney problems
  - are 65 years of age or older
  - take medicines to lower your blood pressure, including diuretics (water pills)
- **Ketoacidosis (increased ketones in your blood or urine).** Ketoacidosis has happened in people who have **type 1 diabetes or type 2 diabetes**, during treatment with empagliflozin, one of the medicines in Empagliflozin and metformin hydrochloride extended-release tablets.

Ketoacidosis is a serious condition, which may need to be treated in a hospital. Ketoacidosis may lead to death. Ketoacidosis can happen with Empagliflozin and metformin hydrochloride extended-release tablets even if your blood sugar is less than 250

mg/dL. Stop taking Empagliflozin and metformin hydrochloride extended-release tablets and call your doctor right away if you get any of the following symptoms:

- nausea
- tiredness
- vomiting
- trouble breathing
- stomach-area (abdominal) pain

If you get any of these symptoms during treatment with Empagliflozin and metformin hydrochloride extended-release tablets, if possible, check for ketones in your urine, even if your blood sugar is less than 250 mg/dL.

- **Kidney problems.** Sudden kidney injury has happened to people taking Empagliflozin and metformin hydrochloride extended-release tablets. Talk to your doctor right away if you:
  - reduce the amount of food or liquid you drink for example, if you are sick or cannot eat or
  - start to lose liquids from your body for example, from vomiting, diarrhea or being in the sun too long
- **Serious urinary tract infections.** Serious urinary tract infections that may lead to hospitalization have happened in people who are taking empagliflozin, one of the medicines in Empagliflozin and metformin hydrochloride extended-release tablets. Tell your doctor if you have any signs or symptoms of a urinary tract infection such as a burning feeling when passing urine, a need to urinate often, the need to urinate right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Sometimes people also may have a fever, back pain, nausea or vomiting.
- **Low blood sugar (hypoglycemia).** If you take Empagliflozin and metformin hydrochloride extended-release tablets 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 dose of your sulfonylurea medicine or insulin may need to be lowered while you take Empagliflozin and metformin hydrochloride extended-release tablets. Signs and symptoms of low blood sugar may include:
  - headache
  - irritability
  - confusion
  - dizziness
  - drowsiness
  - hunger
  - shaking or feeling jittery
  - sweating
  - weakness
  - fast heartbeat
- **Vaginal yeast infection.** Women who take Empagliflozin and metformin hydrochloride extended-release tablets may get vaginal yeast infections. Symptoms of a vaginal yeast infection include vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), or vaginal itching.
- **Yeast infection of the penis (balanitis).** Men who take Empagliflozin and metformin hydrochloride extended-release tablets may get a yeast infection of the skin around the penis. Certain men who are not circumcised may have swelling of the penis that makes it difficult to pull back the skin around the tip of the penis. Other symptoms of yeast infection of the penis include redness, itching, or swelling of the penis, rash of the penis, foul smelling discharge from the penis, or pain in the skin around the penis.

**Talk to your doctor about what to do if you get symptoms of a yeast infection of the vagina or penis.** Your doctor may suggest you use an over-the-counter antifungal medicine. Talk to your doctor right away if you use an over-the-counter antifungal medication and your symptoms do not go away.

- **Allergic (hypersensitivity) reactions.** Serious allergic reactions have happened in people who are taking empagliflozin, one of the medicines in Empagliflozin and metformin hydrochloride extended-release tablets. Symptoms may include
  - swelling of your face, lips, throat and other areas of your skin
  - difficulty with swallowing or breathing.
  - raised, red areas on your skin (hives)

If you have any of these symptoms, stop taking Empagliflozin and metformin hydrochloride extended-release tablets and call your doctor right away or go to the nearest hospital emergency room.

- **Low vitamin B<sub>12</sub> (vitamin B<sub>12</sub> deficiency).** Using metformin for long periods of time may cause a decrease in the amount of vitamin B<sub>12</sub> in your blood, especially if you have had low vitamin B<sub>12</sub> blood levels before. Your doctor may do blood tests to check your vitamin B<sub>12</sub> levels.
- **Increased fats in your blood (cholesterol)**

**Other common side effects** of Empagliflozin and metformin hydrochloride extended-release tablets include diarrhea, nausea, vomiting, gas, stomach pain, indigestion, weakness, and headache.

These are not all the possible side effects of Empagliflozin and metformin hydrochloride extended-release tablets. For more information, ask your doctor or pharmacist.

#### 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. You can also report side effects directly via the local reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Empagliflozin and metformin hydrochloride extended-release tablets**

Do not store above 30°C.

## **6. Contents of the pack and other information**

### **What Empagliflozin and metformin hydrochloride extended-release tablets contain**

**Active Ingredients:** empagliflozin and metformin hydrochloride

**Inactive Ingredients:** *Empagliflozin and metformin hydrochloride extended-release tablets 5 mg/1000 mg:* hydroxy propyl methylcellulose, polyethylene oxide, magnesium stearate, polyethylene glycol, opadry II complete film coating system 47A180001 white, opadry QX quick and flexible film coating system 321A530005 orange and purified water. *Empagliflozin and metformin hydrochloride extended-release tablets 10 mg/1000 mg:* hydroxy propyl methylcellulose, polyethylene oxide, magnesium stearate, polyethylene glycol, opadry II



complete film coating system 47A180001 white, opadry QX quick and flexible film coating system 321A540010 pink and purified water. *Empagliflozin and metformin hydrochloride extended-release tablets 12.5 mg/1000 mg*: hydroxy propyl methylcellulose, polyethylene oxide, magnesium stearate, polyethylene glycol, opadry II complete film coating system 47A100001 white, opadry QX quick and flexible film coating system 321A540011 pink and purified water. *Empagliflozin and metformin hydrochloride extended-release tablets 25 mg/1000 mg*: hydroxy propyl methylcellulose, polyethylene oxide, magnesium stearate, polyethylene glycol, opadry II complete film coating system 47A180001 white, opadry QX quick and flexible film coating system 321A520009 yellow and purified water.

### **What Empagliflozin and metformin hydrochloride extended-release tablets look like and contents of the pack**

#### *Empagliflozin and metformin hydrochloride extended-release tablets 5 mg/1000 mg*

Peach, oval shaped, film coated tablet, printed on one side with C585 and plain on other side.

1. 60's Count: 150 cc round white HDPE container with blue child resistant closure having induction seal.
2. 180's Count: 500 cc round white HDPE container with white child resistant closure having induction seal.

#### *Empagliflozin and metformin hydrochloride extended-release tablets 10 mg/1000 mg*

Dark pink, oval shaped, film coated tablet, printed on one side with C586 and plain on other side.

1. 30's Count:75 cc round white HDPE container with blue child resistant closure having induction seal.
2. 90's Count:250 cc round white HDPE container with white child resistant closure having induction seal.

#### *Empagliflozin and metformin hydrochloride extended-release tablets 12.5 mg/1000 mg*

Light pink, oval shaped, film coated tablet, printed on one side with C588 and plain on other side.

1. 60's Count:150 cc round white HDPE container with blue child resistant closure having induction seal.
2. 180's Count:500 cc round white HDPE container with white child resistant closure having induction seal.

#### *Empagliflozin and metformin hydrochloride extended-release tablets 25 mg/ 1000 mg*

Yellow, oval shaped, film coated tablet, printed on one side with C587 and plain on other side.

1. 30's Count:75 cc round white HDPE container with blue child resistant closure having induction seal.
2. 90's Count:250 cc round white HDPE container with white child resistant closure having induction seal.

**Marketing Authorisation Holder**

Cipla Ltd

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