

EMFLODIAZ FILM-COATED TABLETS

Empagliflozin (10mg, 25mg)

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1. What *Emflodiaz* is used for Type 2 diabetes mellitus

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

- *Emflodiaz* is used to treat type 2 diabetes in adult patients (aged 18 years and older) that cannot be controlled by diet and exercise alone.
 - *Emflodiaz* can be used without other medicines in patients who cannot take metformin (another diabetes medicine).
 - *Emflodiaz* can also be used with other medicines. This may be medicines taken by mouth or insulin given by injection.
 - *Emflodiaz* is used to reduce the risk of cardiovascular death in adult patients with type 2 diabetes and established heart (cardiovascular) disease.
- It is important that you continue with your diet and exercise plan as told by your doctor, pharmacist or nurse.

Heart failure

Emflodiaz is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV), when the heart cannot pump enough blood to the rest of your body.

Chronic kidney disease

Emflodiaz is used to treat chronic kidney disease in adult patients.

2. How *Emflodiaz* works

Emflodiaz contains the active substance empagliflozin which works by blocking a protein in the kidney called sodium-glucose co-transporter 2 (SGLT2). SGLT2 prevents glucose from being excreted in urine by absorbing glucose into the bloodstream as blood is being filtered in the kidneys. By blocking this protein, the medicine causes glucose

(blood sugar), to be removed via urine and blood glucose level, which are too high because of your type 2 diabetes, are thereby reduced. It can reduce left ventricular wall stress and beneficial effects on cardiac remodeling, filling pressures and diastolic function. Therefore, it also can prevent heart failure in patients with or without type 2 diabetes mellitus.

Chronic kidney disease is a long-term condition. It might be caused by other diseases such as diabetes and high blood pressure or even by your own immune system attacking the kidneys. When you have chronic kidney disease, your kidneys may gradually lose their ability to clean and filter the blood properly. This can lead to serious medical problems such as swollen legs, heart failure or need for hospital care. *Emflodiaz* helps protect your kidneys from losing their function.

3. Before you use *Emflodiaz*

- *When you must not use it*

If you are allergic to empagliflozin or any of the other ingredients of this medicine (listed in section Product description)

Pregnancy and lactation

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. Do not use *Emflodiaz* if you are pregnant. It is unknown if *Emflodiaz* is harmful to the unborn child. Do not use *Emflodiaz* if you are breast-feeding. It is not known if *Emflodiaz* passes into human breast milk.

Children and adolescents

Emflodiaz is not recommended for children and adolescents under 18 years, because it has not been studied in these patients.

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.

Kidney function

Your kidney should be checked before you start taking and whilst you are taking

this medicine.

Urine glucose

Because of how this medicine works, your urine will test positive for sugar while you are taking this medicine.

- *Before you start use it*

Talk to your doctor, pharmacist or nurse before taking *Emflodiaz*:

- if you have “type 1 diabetes” – this type usually starts when you are young and your body does not produce any insulin. You should not take *Emflodiaz* if you have type 1 diabetes.
- 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 in your breath, a sweet or metallic taste in your mouth, or a different odour in your urine or sweat, contact a doctor or the nearest hospital straight away. These symptoms could be a sign of “ketoacidosis” – a serious, sometime life-threatening problem you can get because of increased levels of “ketone bodies” in your urine or blood, seen in tests. The risk of developing ketoacidosis may be increased with prolong fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin doses, or a higher need of insulin due to major surgery or serious illness.
- if you have serious kidney problems – your doctor may limit your dose to 10mg once a day or ask you to take a different medicine.
- if you have serious liver problems – your doctor may ask you to take a different medicine.
- Might be at risk of dehydration, for examples:
 - if you are 75 years old or older.
 - if you are being sick, have diarrhea or fever, if you are not able to eat or drink.
 - if you are taking medicines that increase urine production [diuretics] or lower blood pressure

Possible signs are listed in section 6 under ‘Dehydration’. Your doctor may ask you to stop taking *Emflodiaz* until you recover to prevent loss of too much body fluid. Ask about ways to prevent dehydration.

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- if you have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking *Emflodiaz* 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.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is important to tell your doctor

- If you are taking medicine used to remove water from the body (diuretic). Your doctor may ask you to stop taking *Emflodiaz*. Possible signs of losing too much fluid from your body are listed in section Side effects.
- if you are taking other medicines that lower the amount of sugar in your blood such as insulin or a "sulphonylurea" medicine. Your doctor may want to lower the dose of these other medicines, to prevent your blood sugar levels from getting too low (hypoglycaemia).
- if you are taking lithium because *Emflodiaz* can lower the amount of lithium in your blood.

4. How to use *Emflodiaz*

- How much to use

- The recommended dose of *Emflodiaz* is one 10 mg tablet once a day. If you have type 2 diabetes mellitus, your doctor will decide whether to increase your dose to 25 mg once a day, if needed, to help to control your blood sugar.
- Your doctor may limit your dose to 10 mg tablet once a day if you have a kidney problem.
- Your doctor will prescribe the

strength that is right for you. Do not change your dose unless your doctor has told you to.

- When to use it

- Swallow the tablet whole with water
- You can take the tablet 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.

If you have type 2 diabetes mellitus, your doctor may prescribe *Emflodiaz* together with other diabetes medicine. Remember to take all medicines as directed by your doctor to achieve the best results for your health. Appropriate 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 *Emflodiaz*.

- How long to use it

Continue taking *Emflodiaz* for as long as your doctor recommends.

- If you forget to use it

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 *Emflodiaz* 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 *Emflodiaz* to make up for a forgotten dose.

- If you use too much (overdose)

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

5. While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Emflodiaz*.

Tell your doctor immediately if you become pregnant while taking this medication.

Seek **immediate** medical attention when symptoms such as nausea, vomiting, decreased appetite, abdominal pain, excessive thirst, difficulty in breathing, confusion, unusual fatigue or sleepiness, frequent urination and fruity-smelling breath occur.

- Things you must not do

Do not stop taking *Emflodiaz* without first consulting your doctor. If you have type 2 diabetes mellitus, your blood sugar levels may increase when you stop taking *Emflodiaz*.

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

Do not give *Emflodiaz* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

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

Taking this medicine in combination with medicines called sulphonylureas 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 or machines, if you feel dizzy while taking *Emflodiaz*.

Emflodiaz contains lactose

Emflodiaz contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Ketoacidosis

The risk of ketoacidosis must be considered in the event of non-specific symptoms such as nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness. Patients should be assessed for ketoacidosis immediately if these symptoms occur, regardless of blood glucose level. Discontinuation or

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temporary interruption of *Emflodiaz* should be considered, until the situation is clarified.

5. 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:

Severe allergic reaction, seen uncommonly (may affect up to 1 in 100 people)

Possible signs of severe allergic reaction may include:

- swelling of the face, lips, mouth, tongue, or throat that may lead to difficulty breathing or swallowing

Ketoacidosis, seen uncommonly (may affect up to 1 in 100 people)

These are the signs of ketoacidosis (see also section *Before you start use it*):

- 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 *Emflodiaz*.

Contact your doctor as soon as possible if you notice the following side effects:

Low blood sugar (hypoglycemia), seen very commonly (may affect more than 1 in 10 people)

If you take *Emflodiaz* with another medicine that can cause low blood sugar, such as a sulphonylurea or insulin, your risk of getting low blood sugar is higher. 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 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 *Emflodiaz* 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.

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

The signs of dehydration are not specific, however, but may include:

- unusual thirst
- lightheadedness or dizziness upon standing
- fainting or loss of consciousness

Other side effects while taking Emflodiaz:

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 blisters
- thirst
- blood tests may show changes in blood fat (cholesterol) levels in your blood.
- Constipation

Uncommon

- hives
- straining or pain when emptying the bladder
- blood tests may show a decrease in kidney function (creatinine or urea)
- blood tests may show increases in the amount of red blood cells in your blood (haematocrit)

Rare

- 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 visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

6. Storage and Disposal of *Emflodiaz*

- Storage

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. Product Description

- What it looks like

10mg : Pale yellow, round, biconvex, bevel-edged film-coated tablets. Debossed on one side with Boehringer Ingelheim company symbol and “S10” on other side.

25mg : Pale yellow, oval, biconvex, film-coated tablets. Debossed on one side with Boehringer Ingelheim company symbol and “S25” on other side.

- Ingredients

- Active ingredient: Empagliflozin
 - Inactive ingredients:
 Tablet core: *Lactose Monohydrate (Pharmatose 200M)*, *Microcrystalline cellulose (Avicel PH 101)*, *Croscarmellose Sodium*, *Hdroxypropyl cellulose (Klucel EF)*, *Colloidal Silicon dioxide (Aerosil 200 Pharma)*, *Magnesium Stearate*

Film coating (Opadry Yellow - 02B620014-CN): Hypromellose 2910, Titanium dioxide, Iron Oxide Black, Macrogol 400, Iron oxide yellow

- MAL number:

10mg: xxxxxxxx

25mg: xxxxxx

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8. **Manufacturer**

Dr. Reddy's Laboratories Ltd.,
Formulation Tech Ops – II, Survey
No
42p,43,44p,45p,46p,53,54&83, Bac
hupally Village, Bachupally
Mandal,
Medchal – Malkajgiri District,
Pincode 500090, Telangana State,
India

9. **Product Registration Holder**

Dr. Reddy's Laboratories Malaysia
Sdn.Bhd, UNIT NO. SO-29-07
AND SO-29-08, MENARA 1,
STRATA OFFICE, NO. 3, JALAN
BANGSAR, KL ECO CITY,
59200 KUALA LUMPUR,
MALAYSIA

10. **Date of revision**

23/01/2025

11. **Serial number**

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