

1.3.2 PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

LOSUGBY 10 mg and LOSUGBY 25 mg film coated tablets

Empagliflozin

Read all of this leaflet carefully before you start taking **LOSUGBY**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **LOSUGBY** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What **LOSUGBY** is and what it is used for
2. What you need to know before you take **LOSUGBY**
3. How to take **LOSUGBY**
4. Possible side effects
- 5 How to store **LOSUGBY**
6. Contents of the pack and other information

1. What **LOSUGBY** is and what it is used for

- **LOSUGBY** is a medicine which is taken by mouth to treat high blood sugar levels. The active ingredient in **LOSUGBY**, empagliflozin, works by blocking a protein in the kidneys called sodium glucose cotransporter 2 (SGLT2).
- **LOSUGBY** is used to treat 'type 2 diabetes' in adults (aged 18 years and older) to improve blood sugar (glucose) control together with diet and exercise.
- **LOSUGBY** can be used alone or can also be taken with other medicines used to lower your blood sugar. These may be medicines taken by mouth or insulin given by injection.

2. What you need to know before you take LOSUGBY

Do not take LOSUGBY:

- if you are allergic to empagliflozin or any of the other ingredients of **LOSUGBY** (listed in section 6).
- If you have type 1 diabetes.
- If you have increased levels of ketone bodies in your urine or blood (see Warnings and precautions).
- If you have moderate or severe kidney problems, or have kidney failure and are on renal dialysis.
- If you are pregnant or if you are breast feeding your baby.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking **LOSUGBY**, and during treatment:

- 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 the 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 diabetic 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 have serious kidney or liver problems – your doctor may ask you to take a different medicine.
- if you are being sick, have diarrhoea or fever, or if you are not able to eat or drink
- if you are taking medicines that increase urine production [diuretics] or lower blood

pressure

- if you are over 75 years old.

Your doctor may ask you to stop taking **LOSUGBY** until you recover to prevent loss of too much body fluid. Ask about ways to prevent dehydration.

- if you are 85 years old or older as you should not start taking **LOSUGBY**.
- if you have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking **LOSUGBY** 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.

Foot care

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 **LOSUGBY** works, your urine will test positive for sugar while you are taking **LOSUGBY**.

Children and adolescents

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

Other medicines and LOSUGBY [LOSUGBY**]**

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

- if you are taking medicines that increase urine production (diuretics). Your doctor may ask you to stop taking **LOSUGBY**.

- 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).

Pregnancy and breast-feeding

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

Driving and using machines

LOSUGBY 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 **LOSUGBY**.

LOSUGBY contains lactose:

If you have an intolerance to some sugars, contact your doctor before taking **LOSUGBY**.

3. How to take LOSUGBY

Always take **LOSUGBY** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended starting dosage of **LOSUGBY** is one 10 mg tablet once a day. Your doctor may tell you to increase the dose to 25 mg once a day if your blood glucose is not adequately controlled with a dose of 10 mg per day.

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

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.

Continue to take **LOSUGBY** as long as your doctor prescribes it so you can continue to help control your blood sugar. Your doctor may prescribe **LOSUGBY** together with other diabetes medicines. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

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 healthcare professional while taking **LOSUGBY**.

Check your blood sugar as your healthcare professional tells you if you have the impression that the effect of **LOSUGBY** is too strong, or too weak, talk to your doctor, pharmacist or nurse.

If you take more LOSUGBY than you should

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

If you forget to take LOSUGBY

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

If you stop taking LOSUGBY

Do not stop taking **LOSUGBY** without first consulting your doctor. Your blood sugar levels may increase when you stop taking **LOSUGBY**.

4. Possible side effects

LOSUGBY can cause side effects

Not all side effects reported for **LOSUGBY** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **LOSUGBY**, please consult your health care provider for advice.

Stop taking **LOSUGBY** and see a doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following serious or potentially serious side effects:

- any sign of an allergic reaction (hypersensitivity) such as skin rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, and wheezing and shortness of breath.
- any sign of ketoacidosis such as
 - 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 your blood glucose (sugar) level. Your doctor may decide to temporarily or permanently stop your treatment with **LOSUGBY**.

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

- Low blood sugar (hypoglycaemia), seen frequently when taking **LOSUGBY** with a sulphonylurea or with insulin.

The signs of low blood sugar may include:

- jitteriness, sweating, feeling very anxious or confused, fast heartbeat

- excessive hunger, headache.
- Urinary tract infection

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)

- Dehydration

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

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

Other side effects while taking **LOSUGBY**:

Frequent

- 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 an increase in blood fat (cholesterol) levels in your blood

Less frequent

- 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)

Frequency unknown

- 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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **LOSUGBY**.

5. How to store LOSUGBY

Store all medicines out of reach of children.

Store at or below 25 °C

Store in the original package in order to protect from moisture

Keep container well closed.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Ask your pharmacist how to dispose of medicines you no longer use.

6. Contents of the pack and other information

What LOSUGBY contains

- The active substance is empagliflozin
- Contains sugar (lactose monohydrate 42,96 mg per 10 mg tablet or 107,40 mg per 25 mg tablet)
- The other ingredients are:
 - *Tablet core*: Microcrystalline cellulose, povidone, Croscarmellose sodium, Colloidal silicon dioxide, Magnesium stearate
 - *Film coat*: Hypromellose, Titanium dioxide, Talc, Macrogol, Iron oxide yellow

What LOSUGBY looks like and contents of the pack

LOSUGBY 10 mg: Pale Yellow, round, biconvex film-coated tablets debossed with "10" on one side and "A" on other side

LOSUGBY 25 mg: Pale Yellow, oval, biconvex film-coated tablets debossed with "25" on one side and "A" on other side

LOSUGBY 10 and 25 mg is available in PVC/PVDC-peel push blister pack or HDPE

Container with 33mm CR closure

Pack sizes of 10, 28, 30, 56, 60, 90 film-coated tablets Not all pack sizes may be marketed.

Holder of Certificate of Registration

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