Package leaflet: Information for the patient

Dapagliflozin 5 mg film-coated tablets
Dapagliflozin 10 mg film-coated tablets
dapagliflozin

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Dapagliflozin is and what it is used for

What Dapagliflozin is
Dapagliflozin contains the active substance dapagliflozin. It belongs to a group of medicines called "sodium glucose co-transporter-2 (SGLT2) inhibitors". They work by blocking the SGLT2 protein in your kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from your body via the urine.

What Dapagliflozin is used for
Dapagliflozin is used to treat:

- **Type 2 diabetes**
  - in adults and children aged 10 years and older.
  - if your type 2 diabetes cannot be controlled with diet and exercise.
  - Dapagliflozin can be used on its own or together with other medicines to treat diabetes.
  - It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

What is type 2 diabetes and how does Dapagliflozin help?
- In type 2 diabetes your body does not make enough insulin or is not able to use the insulin it makes properly. This leads to a high level of sugar in your blood. This can lead to serious problems like heart or kidney disease, blindness, and poor circulation in your arms and legs.
- Dapagliflozin works by removing excess sugar from your body.

2. What you need to know before you take Dapagliflozin

Do not take Dapagliflozin
- if you are allergic to dapagliflozin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Contact a doctor or the nearest hospital straight away

Diabetic ketoacidosis:

- If you have diabetes and experience 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 or rapid weight loss.
- The above 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.
- When you are treated with Dapagliflozin, diabetic ketoacidosis can occur even if your blood sugar is normal.

If you suspect you have diabetic ketoacidosis, contact a doctor or the nearest hospital straight away and do not take this medicine.

Necrotising fasciitis of the perineum:

- 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.

Talk to your doctor, pharmacist or nurse before taking Dapagliflozin

- if you have "type 1 diabetes" – the type that usually starts when you are young, and your body does not produce any insulin. Dapagliflozin should not be used to treat this condition.
- if you have diabetes and have a kidney problem – your doctor may ask you to take additional or a different medicine to control your blood sugar.
- if you have a liver problem – your doctor may start you on a lower dose.
- if you are on medicines to lower your blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). More information is given below under 'Other medicines and Dapagliflozin'.
- if you have very high levels of sugar in your blood which may make you dehydrated (lose too much body fluid). Possible signs of dehydration are listed in section 4. Tell your doctor before you start taking Dapagliflozin if you have any of these signs.
- if you have or develop nausea (feeling sick), vomiting or fever or if you are not able to eat or drink. These conditions can cause dehydration. Your doctor may ask you to stop taking Dapagliflozin until you recover to prevent dehydration.
- if you often get infections of the urinary tract.

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Dapagliflozin.

Diabetes and foot care
If you have diabetes, 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 Dapagliflozin works, your urine will test positive for sugar while you are on this medicine.

Children and adolescents

Dapagliflozin 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.

Dapagliflozin is not recommended for children and adolescents under 18 years of age for the treatment of heart failure or for the treatment of chronic kidney disease, because it has not been studied in these patients.

Other medicines and Dapagliflozin
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.
Especially tell your doctor:
- if you are taking a medicine used to remove water from the body (diuretic).
- 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 you from getting low blood sugar levels (hypoglycaemia).
- if you are taking lithium because Dapagliflozin can lower the amount of lithium in your blood.

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. You should stop taking this medicine if you become pregnant, since it is not recommended during the second and third trimesters of pregnancy. Talk to your doctor about the best way to control your blood sugar while you are pregnant.

Talk to your doctor if you would like to or are breast-feeding before taking this medicine. Do not use Dapagliflozin if you are breast-feeding. It is not known if this medicine passes into human breast milk.

Driving and using machines
Dapagliflozin has no or negligible influence on the ability to drive and use machines.

Taking this medicine with other medicines called sulphonylureas or with insulin can cause too low blood sugar levels (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 taking Dapagliflozin.

Dapagliflozin contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Dapagliflozin contains isomalt
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dapagliflozin

Always take this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How much to take
- The recommended dose is one 10 mg tablet each day.
- Your doctor may start you on a 5 mg dose if you have a liver problem.
- Your doctor will prescribe the strength that is right for you.

Taking this medicine
- Swallow the tablet whole with half a glass of water.

- You can take your 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.

Your doctor may prescribe Dapagliflozin together with other medicine(s). Remember to take these other medicine(s) as your doctor has told you. This will help get the best results for your health.

Diet and exercise can help your body use its blood sugar better. If you have diabetes, it is important to stay on any diet and exercise program recommended by your doctor while taking Dapagliflozin.

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

If you forget to take Dapagliflozin
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 a dose of Dapagliflozin 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 Dapagliflozin to make up for a forgotten dose.

If you stop taking Dapagliflozin
Do not stop taking Dapagliflozin without talking to your doctor first. If you have diabetes, your blood sugar may increase without this medicine.

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

4. Possible 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:

- **angioedema,** seen very rarely (may affect up to 1 in 10,000 people).
  These are signs of angioedema:
  - swelling of the face, tongue or throat
  - difficulties swallowing
  - hives and breathing problems

- **diabetic ketoacidosis** - this is rare in patients with type 2 diabetes (may affect up to 1 in 1,000 people).
  These are the signs of diabetic ketoacidosis (see also section 2 Warnings and precautions):
  - increased levels of "ketone bodies" in your urine or blood
  - 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
- rapid weight loss.

This may occur regardless of blood sugar level. Your doctor may decide to temporarily or permanently stop your treatment with Dapagliflozin.

- **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, seen very rarely.

Stop taking Dapagliflozin and see a doctor as soon as possible if you notice any of the following serious side effects:

- **urinary tract infection,** seen commonly (may affect up to 1 in 10 people).
  These are signs of a severe infection of the urinary tract:
  - fever and/or chills
  - burning sensation when passing water (urinating)
  - pain in your back or side.

Although uncommon, if you see blood in your urine, tell your doctor immediately.

Contact your doctor as soon as possible if you have any of the following side effects:

- **low blood sugar levels** (hypoglycaemia), seen very commonly (may affect more than 1 in 10 people) in patients with diabetes taking this medicine with a sulphonylurea or insulin.
  These are the signs of low blood sugar:
  - shaking, sweating, feeling very anxious, fast heart beat
  - feeling hungry, headache, change in vision
  - a change in your mood or feeling confused.

Your doctor will tell you how to treat low blood sugar levels and what to do if you get any of the signs above.

Other side effects when taking Dapagliflozin:

Common
- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- back pain
- passing more water (urine) than usual or needing to pass water more often
- changes in the amount of cholesterol or fats in your blood (shown in tests)
- increases in the amount of red blood cells in your blood (shown in tests)
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment
- dizziness
- rash

Uncommon (may affect up to 1 in 100 people)
- loss of too much fluid from your body (dehydration, signs may include very dry or sticky mouth, passing little or no urine or fast heartbeat)
- thirst
- constipation
- awakening from sleep at night to pass urine
- dry mouth
- weight decreased
- increases in creatinine (shown in laboratory blood tests) in the beginning of treatment
- increases in urea (shown in laboratory blood tests)

Very rare
- inflammation of the kidneys (tubulointerstitial nephritis)

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dapagliflozin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister or carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Dapagliflozin contains

- The active substance is dapagliflozin.
  Each Dapagliflozin 5 mg film-coated tablet (tablet) contains dapagliflozin propylene glycol monohydrate equivalent to 5 mg dapagliflozin.
  Each Dapagliflozin 10 mg film-coated tablet (tablet) contains dapagliflozin propylene glycol monohydrate equivalent to 10 mg dapagliflozin.
- The other ingredients are:
  - tablet core: microcrystalline cellulose, lactose, crospovidone Type-A, Silica, Colloidal Anhydrous (E551), sodium stearyl fumarate.
  - film-coating: rice starch, isomalt (E953), hypromellose 6 mPas (E464), hypromellose 15 mPas (E464), triglycerides medium chain, iron oxide yellow (E172).

What Dapagliflozin looks like and contents of the pack

Dapagliflozin 5 mg film-coated tablets are yellow to light yellow biconvex round shaped film coated tablets (diameter approx. 7 mm) plain on both sides.

Dapagliflozin 10 mg film-coated tablets are yellow to light yellow biconvex round shaped film coated tablet (diameter approx. 9 mm) debossed with ' | ' on one side and plain on other side.

Dapagliflozin 5 mg tablets are available in blisters in pack sizes of 14, 28, 30, 90, 98 or 100 film-coated tablets.
Dapagliflozin 10 mg tablets are available in blisters in pack sizes of 10, 14, 28, 30, 56, 90, 98 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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