Package leaflet: Information for the patient

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

1. What Dapagliflozin Rowex is and what it is used for

What Dapagliflozin Rowex is
Dapagliflozin Rowex 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 Rowex is used for
Dapagliflozin Rowex 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 Rowex 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.

- **Heart failure**
  - in adults (aged 18 years and older) when the heart does not pump blood as well as it should.

- **Chronic kidney disease**
  - in adults with reduced kidney function.

What is type 2 diabetes and how does Dapagliflozin Rowex 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 Rowex works by removing excess sugar from your body. It can also help prevent heart disease.

What is heart failure and how does Dapagliflozin Rowex help?
- This type of heart failure occurs when the heart does not pump blood to the lungs and the rest of the body as well as it should. This can lead to serious medical problems and need for hospital care.
- The most common symptoms of heart failure are feeling breathless, feeling tired or very tired all the time, and ankle swelling.
- Dapagliflozin Rowex helps protect your heart from getting worse and improves your symptoms. It can lower the need to go to hospital and can help some patients to live longer.

What is chronic kidney disease and how does Dapagliflozin Rowex help?
- When you have chronic kidney disease, your kidneys may gradually lose their function. This means they would not be able to clean and filter your blood the way they should. Loss of kidney function can lead to serious medical problems and need for hospital care.
- Dapagliflozin Rowex helps protect your kidneys from losing their function. That can help some patients to live longer.

2. What you need to know before you take Dapagliflozin Rowex

Do not take Dapagliflozin Rowex 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 Rowex, 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 Rowex

- if you have “type 1 diabetes” – the type that usually starts when you are young, and your body does not produce any insulin Dapagliflozin Rowex 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 Rowex’ 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 Rowex 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 Rowex 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 Rowex.

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 Rowex works, your urine will test positive for sugar while you are on this medicine.

Children and adolescents
Dapagliflozin Rowex 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 Rowex 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 Rowex
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 Rowex 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 Rowex if you are breast-feeding. It is not known if this medicine passes into human breast milk.

Driving and using machines
Dapagliflozin Rowex 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 Rowex.

Dapagliflozin Rowex contains lactose and sodium
Dapagliflozin Rowex 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.

This medicine contains less than 1 mmol sodium (23 mg) per dose unit, that is to say essentially 'sodium free'.

3. How to take Dapagliflozin Rowex

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, do not chew or break the tablet.
- 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 Rowex 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 Rowex.

If you take more Dapagliflozin Rowex than you should
If you take more Dapagliflozin Rowex 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 Rowex
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 Rowex 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 Rowex to make up for a forgotten dose.

If you stop taking Dapagliflozin Rowex
Do not stop taking Dapagliflozin Rowex 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 Rowex.

- **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 Rowex 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 heartbeat
  - 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 Rowex
Common (may affect up to 1 in 10 people)
- 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 (may affect up to 1 in 10,000 people)
- inflammation of the kidneys (tubulointerstitial nephritis).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dapagliflozin Rowex

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 protect the environment.

6. Contents of the pack and other information

What Dapagliflozin Rowex contains
The active substance is dapagliflozin.
Each Dapagliflozin Rowex 5 mg film-coated tablet contains 5 mg dapagliflozin.
Each Dapagliflozin Rowex 10 mg film-coated tablet contains 10 mg dapagliflozin.

The other ingredients are:
tablet core: Hypromellose 2910, lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, magnesium stearate.
film-coating: Hypromellose 2910, hydroxypropyl cellulose, triethyl citrate, titanium dioxide (E171), iron oxide yellow (E172).

What Dapagliflozin Rowex looks like and contents of the pack
Dapagliflozin Rowex 5 mg film-coated (tablets) are light yellow, round, biconvex film-coated tablet debossed with “DN 5” on one side. Tablet diameter: 7 mm.

Dapagliflozin Rowex 10 mg film-coated (tablets) are light yellow, oval, biconvex film-coated tablet debossed with “DN 10” on one side. Tablet length: 12 mm, tablet width: 6 mm.

Dapagliflozin Rowex 5 mg film-coated tablets (tablet)
oPA/Alu/PVC//Alu blisters containing 10, 14, 28, 98 or 100 film-coated tablets, or oPA/Alu/PVC//Alu perforated unit-dose blisters containing 30 x 1, or 90 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Dapagliflozin Rowex 10 mg film-coated tablets (tablet)
oPA/Alu/PVC//Alu blisters containing 14, 28, 98 or 100 film-coated tablets, or oPA/Alu/PVC//Alu perforated unit-dose blisters containing 10 x1, 30 x 1, or 90 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer
Lek S.A., Ul. Podlipie 16 Strykow, Lodzkie 95-010, Poland.

This medicine is authorised in the Member States of the European Economic Area under the following names:

AT	Dapagliflozin Sandoz 5 mg – Filmtabletten Dapagliflozin Sandoz 10 mg – Filmtabletten
BE	Dapagliflozin Sandoz 5 mg filmomhulde tabletten Dapagliflozin Sandoz 10 mg filmomhulde tabletten
BG	Dapagliflozin Sandoz 5 mg film-coated tablets Дапаглифлозин Сандоз 5 mg филмирани таблетки Dapagliflozin Sandoz 10 mg film-coated tablets

	Дапаглифлозин Сандоз 10 mg филмирани таблетки
CY	Dapagliflozin / Sandoz
CZ	Dapagliflozin Sandoz
	Dapagliflozin Sandoz
DE	Dapagliflozin - 1 A Pharma 5 mg Filmtabletten
	Dapagliflozin - 1 A Pharma 10 mg Filmtabletten
DK	Dapagliflozin Sandoz
EL	Dapagliflozin / Sandoz
ES	Dapagliflozina Sandoz 5 mg comprimidos recibuertos con película EFG
	Dapagliflozina Sandoz 10 mg comprimidos recibuertos con película EFG
FI	Dapagliflozin Sandoz 5 mg tabletti kalvopäällysteinen
	Dapagliflozin Sandoz 10 mg tabletti kalvopäällysteinen
FR	DAPAGLIFLOZINE SANDOZ 10 mg, comprimé pelliculé
HU	Dapagliflozin Sandoz 10mg filmtabletta
IE	Dapagliflozin Rowex 5 mg film-coated tablets
	Dapagliflozin Rowex 10 mg film-coated tablets
IS	Dapagliflozin Sandoz
IT	Dapagliflozin Sandoz
MT	Dapagliflozin Sandoz 5 mg film-coated tablets
	Dapagliflozin Sandoz 10 mg film-coated tablets
NL	Dapagliflozine Sandoz 5 mg, filmomhulde tabletten
	Dapagliflozine Sandoz 10 mg, filmomhulde tabletten
NO	Dapagliflozin Sandoz
PT	Dapagliflozina Sandoz
SE	Dapagliflozin Sandoz

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