

Patient Guide

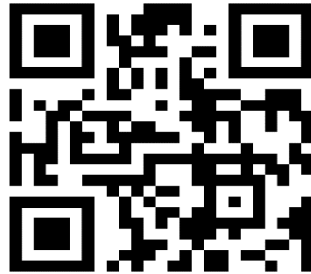
Pafazin Tablets 5mg & 10mg (Dapagliflozin Tablets 5mg & 10mg)

Carry this card with you at all times.

This document provides important information about some of the side effects of Pafazin, what action you can take to prevent them and what you should do if you experience them. This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

You should also read the patient information leaflet which is provided with the medicine pack. It is important that you read the leaflet before you start taking this medicine and each time you get a new pack of Pafazin as it could contain new information.

Please read the below PIL QR Barcode for full patient information leaflet.



This information from Pafazin explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

What is Pafazin and how does it work?

Pafazin (Dapagliflozin) is a drug belonging to the class of SGLT-2 Inhibitor.

Dapagliflozin Tablets 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 Tablets is used for?

Dapagliflozin Tablets is used to treat:

❖ Type 2 diabetes

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

❖ Heart failure

- o In adults (aged 18 years and older) with symptoms due to a weak pump function of the heart.

❖ Chronic kidney disease

- o In adults with reduced kidney function.

What do I need to tell my doctor BEFORE I take this drug?

- ❖ If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- ❖ If you have type 1 diabetes. Do not use this drug to treat type 1 diabetes.
- ❖ If you have an acidic blood problem.
- ❖ If you have kidney disease or are on dialysis.
- ❖ If you are dehydrated, talk with your doctor.
- ❖ If you are taking or have recently taken drugs that suppress your immune system to treat kidney disease.
- ❖ If you are pregnant or may be pregnant. Do not take this drug if you are in the second or third trimester of pregnancy.

- ❖ If you are breast-feeding. Do not breast-feed while you take this drug.
- ❖ This is not a list of all drugs or health problems that interact with this drug. Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug? For all uses of this drug:

Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists. This drug may need to be stopped before certain types of surgery as your doctor has told you. If this drug is stopped, your doctor will tell you when to start taking this drug again after your surgery or procedure.

Do not drive if your blood sugar has been low. There is a greater chance of you having a crash.

- ❖ Too much acid in the blood or urine (ketoacidosis) has happened with this drug. This may need to be treated in the hospital and can be deadly. This can happen even when blood sugar is normal. Patients with some health problems, including diabetes or pancreas problems, have a higher risk of ketoacidosis. Check your ketones as you have been told by the doctor. Talk with the doctor.
- ❖ Severe urinary tract infections (UTIs) have happened with this drug. Sometimes, this needed to be treated in a hospital.
- ❖ Kidney problems have happened. Sometimes, these may need to be treated in the hospital or with dialysis.
- ❖ Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.
- ❖ If you are not able to eat or drink like normal, talk with your doctor. This includes if you are sick, fasting, or you are having certain procedures or surgery.
- ❖ If you cannot drink liquids by mouth or if you have upset stomach, throwing up, or diarrhea that does not go away; you need to avoid getting dehydrated. Contact your doctor to find out what to do. Dehydration may lead to low blood pressure or to new or worse kidney problems.
- ❖ A rare but very bad infection has happened with drugs like this one. This infection may be deadly. Get medical help right away if your genitals or the area between your genitals and rectum becomes tender, red, or swollen, and you have a fever or do not feel well

- ❖ To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.
- ❖ This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- ❖ Talk with your doctor before you drink alcohol.
- ❖ If you are 65 or older, use this drug with care. You could have more side effects.
- ❖ This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

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 Tablets 10 mg, 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 Tablets :

- ❖ if you have “type 1 diabetes” – the type that usually starts when you are young, and your body does not produce any insulin.
- ❖ 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 Tablets 10 mg’.
- ❖ 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 Tablets 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 Tablets 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 Tablets.

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

Children and adolescents

Dapagliflozin Tablets 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 Tablets 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.

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).

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 Tablets if you are breast-feeding. It is not known if this medicine passes into human breast milk.

Driving and using machines

Dapagliflozin Tablets has no or negligible influence on the ability to drive and use machines. Taking this medicine with other medicines called sulphonyl ureas 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 take Dapagliflozin Tablets.

Dapagliflozin Tablets contain lactose

Dapagliflozin Tablets contain 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.

How to take Dapagliflozin Tablets

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.

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 Tablets 10 mg.

If you take more Dapagliflozin Tablets than you should

If you take more Dapagliflozin Tablets 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 Tablets 10 mg

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 Tablets 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 Tablets to make up for a forgotten dose.

If you stop taking Dapagliflozin Tablets

Do not stop taking Dapagliflozin Tablets 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.

What are some other side effects of this drug?

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:

- o swelling of the face, tongue or throat
- o difficulties swallowing
- o 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 Tablets 10 mg.

- ❖ **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 Tablets 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:
 - o fever and/or chills
 - o burning sensation when passing water (urinating)
 - o 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.

How to store Dapagliflozin Tablets

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.

To Report of Any Adverse Event:

If any adverse events received from the patients, then all healthcare professionals are required to strictly report it by contacting the following:

Saudi Food and Drug Authority (SFDA) SFDA call centre: 19999 E-mail: npc.drug@sFDA.gov.sa Website: http://ade.sfda.gov.sa/	Pharmacovigilance Department (PPI) E-mail ID: Abdulrahman@pharma.com.sa & PV@pharma.com.sa Mobile: +966 580303838
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Please complete this section or ask your doctor to do it

- Patient Name: _____
- Patient Birth Date: _____
- Indication: _____
- Dose: _____
- Prescribing Doctor's Name: _____
- Prescribing Doctor's telephone: _____

