

PATIENT INFORMATION LEAFLET

Dapagliflozin Tablets (5/ 10 mg)

OZIN 5/10

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 or pharmacist.
- ❖ 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.

What is in this leaflet:

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

1. What OZIN is and what it is used for

OZIN 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.

OZIN is used to treat:

- ❖ Type 2 diabetes
- ❖ Heart failure
- ❖ Chronic kidney disease

2. What you need to know before you take OZIN

Do not take OZIN if you are allergic to Dapagliflozin.

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. These symptoms could be a sign of "diabetic ketoacidosis"

When you are treated with OZIN, 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.

Talk to your doctor or pharmacist before taking OZIN, if:

- ❖ you have "type 1 diabetes", the type that usually starts when you are young, and your body does not produce any insulin.
- ❖ you are on medicines to lower your blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension).
- ❖ 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.
- ❖ you have a liver problem, your doctor may start you on a lower dose.
- ❖ you have very high levels of sugar in your blood which may make you

dehydrated (lose too much body fluid).

- ❖ 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 OZIN until you recover to prevent dehydration.
- ❖ you often get infections of the urinary tract.

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

Children and adolescents

OZIN 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. OZIN 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 OZIN

Tell your doctor or pharmacist 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).
- ❖ 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 OZIN if you are breast-feeding. It is not known if this medicine passes into human breast milk.

Driving and using machines

OZIN 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 OZIN.

3. How to take OZIN

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist 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.

If you take more OZIN than you should

If you take more OZIN 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 OZIN

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 OZIN 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 OZIN to make up for a forgotten dose.

If you stop taking OZIN

Do not stop taking OZIN 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 or pharmacist

4. What are the possible side effects of OZIN

Like all prescription medicines, OZIN may cause side effects, although not everyone gets them.

Contact a doctor or the nearest hospital straight away if you have any of the following side effects.

Very Common side effects (may affect more than 1 in 10 people)

❖ Low blood sugar levels (hypoglycaemia), seen very commonly 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

Common side effects (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 blood
- ❖ Increases in the amount of red blood cells in blood
- ❖ Decreases in creatinine renal clearance in the beginning of treatment
- ❖ Dizziness
- ❖ Rash

Uncommon side effects (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 in the beginning of treatment in blood

- ❖ Increases in urea in blood

Very Rare side effects (may affect up to 1 in 10,000 people).

❖ Angioedema, seen very rarely.

These are signs of angioedema:

- swelling of the face, tongue or throat
- difficulties swallowing
- hives and breathing problems

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.

5. How to store OZIN

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 and 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 protect the environment.

6. Contents of the pack and other information

What OZIN contains

The active ingredient is Dapagliflozin.

OZIN 5

Each film coated tablet contains:

Dapagliflozin Propanediol Monohydrate equivalent to

Dapagliflozin 5 mg

Colours: Iron Oxide Yellow & Titanium Dioxide

OZIN 10

Each film coated tablet contains:

Dapagliflozin Propanediol Monohydrate equivalent to

Dapagliflozin 10 mg

Colours: Iron Oxide Yellow & Titanium Dioxide

What OZIN looks like and contents of the pack

OZIN is yellow coloured, round, biconvex, film coated tablets with "Q" logo scored on one side. Tablets are packed in Alu-Alu Blister. The pack size is 3x3x10 tablets in a printed paper carton.



Manufactured by :
Quest Pharmaceuticals Pvt. Ltd.
 Chhata Pipara, Bara, Nepal

For further information
Quest Pharmaceuticals Pvt. Ltd.
 Tripureshwar, Kathmandu
 Tel. 01-4240304, Email : quest.ktm@quest.com.np,
 Website : www.quest.com.np