

QTERN[®] 5 MG/10 MG FILM-COATED TABLETS

Saxagliptin 5 mg & Dapagliflozin 10 mg

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What QTERN is used for

QTERN contains the active substances saxagliptin and dapagliflozin. Each belongs to a group of medicines called “oral anti-diabetics”.

- This medicine is taken by mouth for type 2 diabetes mellitus.
- This medicine is used if your type 2 diabetes mellitus cannot be controlled with other oral diabetes medicines, along with diet and exercise.

Type 2 diabetes mellitus

Type 2 diabetes mellitus is a condition in which your body does not make enough insulin and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood and can lead to serious medical problems.

The main goal of treating type 2 diabetes is to control your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, such as heart disease, kidney disease, blindness and amputation.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why QTERN has been prescribed for you.

QTERN is not addictive.

How QTERN works

QTERN contains two active ingredients, saxagliptin and dapagliflozin. Saxagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors), and dapagliflozin belongs to a class of medicines called SGLT-2 (sodium glucose cotransporter-2) inhibitors. Saxagliptin and dapagliflozin together to lower blood sugar levels in patients with type 2 diabetes mellitus.

Before you use QTERN

- When you must not use it

Do not take QTERN if you have an allergy to:

- saxagliptin or dapagliflozin, the active ingredients in QTERN;
- any other DPP-4 inhibitor medicine; or
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin or you may feel faint.

Do not take QTERN if you have poorly functioning kidneys, severe kidney disease or kidney failure. QTERN requires good functioning kidneys to work well.

Do not take QTERN if you have poor liver function or severe liver failure. If you have or have had problems with your liver, tell your doctor before you take any QTERN.

Do not take this medicine if you are pregnant or plan to become pregnant. The safety of QTERN in pregnant women has not been established. Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace QTERN with insulin while you are pregnant. Do not take QTERN if you are breastfeeding. QTERN is not recommended while you are breastfeeding. Your doctor will discuss the options available to you.

Do not take QTERN after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

QTERN is not recommended for use in children. It has not been studied in children younger than 18 years old.

If you are not sure whether you should start taking QTERN, talk to your doctor or pharmacist.

- Before you start to use it

Discard any other medicines containing dapagliflozin or saxagliptin that your doctor might have prescribed to you in the past and that you may still have in your possession. QTERN contains dapagliflozin and saxagliptin. If you have more than one medicine containing dapagliflozin or saxagliptin in your possession, you may accidentally take too much (overdose).

Ask your doctor or pharmacist if you are unsure if you have any other medicines containing dapagliflozin or saxagliptin. Saxagliptin and dapagliflozin are sold separately as ONGLYZA and FORXIGA and may also be sold in combination with metformin as KOMBIGLYZE XR and XIGDUO XR. Your doctor or pharmacist will know which other medicines also contain saxagliptin and dapagliflozin and can tell you what to do.

Tell your doctor if you have any allergies to:

- any other medicines
- any other substances such as foods, dyes or preservatives.

Tell your doctor or pharmacist if you have, or have had, any medical conditions, especially the following:

- type 1 diabetes mellitus that is well controlled by insulin alone
- diabetic ketoacidosis. This is a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood. Seek immediate medical attention when symptoms such as nausea, vomiting, decreased appetite, abdominal pain, excessive thirst, difficulty in breathing, confusion, unusual fatigue or sleepiness, frequent urination, fruity-smelling breath, rapid weight loss, sweet or metallic taste in your mouth, and different odour to your urine and sweat occur.
- heart failure
- kidney, liver or pancreas problems
- you are taking a medicine for high blood pressure or taking a water pill (diuretic)
- frequently get genital or urinary tract infections (infections of the bladder, kidney or tubes that carry urine)
- an illness that will make you dehydrated such as diarrhoea or a severe infection.

Your doctor will do some tests for kidney function at the start of treatment and regularly while you are on treatment.

Tell your doctor if you are pregnant or intend to become pregnant. QTERN is not recommended for use during pregnancy. It is not known if QTERN will harm your unborn baby.

Tell your doctor if you are breastfeeding or plan to breastfeed. QTERN should not be used while breastfeeding or if planning to breastfeed. It is not known if the active ingredients in QTERN will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking QTERN.

Tell your doctor if you are lactose intolerant. QTERN tablets contain lactose.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Especially tell your doctor:

- if you are taking lithium because QTERN can lower the amount of lithium in your blood.

QTERN can be taken with most other medicines.

If you have not told your doctor about any of these things, tell them before you take any QTERN.

How to use QTERN

- How much to use

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

Swallow your QTERN tablet whole with a full glass of water.

QTERN tablets should not be split or cut.

The dose of QTERN is one tablet once a day.

Your doctor may prescribe QTERN along with other medicines that lower blood sugar.

- When to use it

QTERN should be taken at approximately the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

QTERN tablets can be taken with or without food.

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

Make sure you keep enough QTERN to last over weekends and holidays.

QTERN helps control your condition, but does not cure it. Therefore, you must take QTERN every day.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and

Emergency at the nearest hospital, if you think that you or anyone else may have taken too much QTERN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

- Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking QTERN.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking QTERN.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

As for all diabetic patients it is important to check your feet regularly and adhere to any other advice regarding foot care given by your doctor.

Hypoglycaemia

QTERN does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

Hyperglycaemia

If you notice the return of any of the signs of hyperglycaemia, contact your doctor immediately. Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less QTERN than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery).

Your blood glucose may become difficult to control at these times.

If you become pregnant while taking QTERN, tell your doctor immediately.

If you need to have any medical tests while you are taking QTERN, tell your doctor. QTERN may affect the results of some tests.

Visit your doctor regularly for check-ups. Your doctor may want to perform blood tests to check your kidneys, liver, heart, and levels of cholesterol and fats in your blood while you are taking QTERN.

- Things you must not do

Do not take QTERN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

- Things to be careful of

Be careful driving or operating machinery until you know how QTERN affects you. Although rare, QTERN may cause dizziness in some people. Low blood sugar levels may also slow your reaction time and affect your ability to drive or operate machinery.

Make sure you know how you react to QTERN before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking QTERN.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may

have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- nausea, vomiting or diarrhoea
- stomach pain or discomfort
- signs of an infection in the breathing passages including runny nose, sore throat and cough
- soreness in the back of the nose and throat and discomfort when swallowing
- difficulty breathing or tightness in the chest
- feeling depressed or anxious
- joint pain
- signs of anaemia such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- swelling of the hands, feet or ankles
- rash
- loss of appetite
- loss of taste
- back pain.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of hypoglycaemia (low blood sugar) that persist despite administering sugar as described under **WHILE YOU ARE USING IT** in this leaflet. Signs of low blood sugar may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, rapid heartbeat, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers. Do not drive a car if you have signs of low blood sugar.
- severe allergic reaction (may include shortness of breath, wheezing or severe difficulty in breathing; shock, swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives on the skin, hayfever, or you may feel faint).
- volume depletion (loss of needed fluids from the body; dehydration). Tell your doctor if you are unable to keep fluids

down or if you have any of these symptoms of too much loss of body fluids (volume depletion or dehydration) while taking QTERN: dry sticky mouth, severe thirst, severe diarrhoea or vomiting, dizziness, or urinating less often than normal or not at all.

- genital infections. If you take QTERN, you may be at a greater risk for genital infections. Tell your doctor if you experience painful urination, soreness and more severe irritation or redness and swelling of your genitals, or an unpleasant odour or discharge associated with your genitals.
- urinary tract infection. If you take QTERN, you may be at a greater risk for urinary tract infections. If you have symptoms, such as burning or pain when you pass urine, more frequent or urgent need to urinate, fever, chills, or blood in the urine, contact your doctor as soon as possible.
- if you experience pain or tenderness, redness, swelling of the genitals or the area from the genitals to the rectum, fever and generally feeling unwell. These may be symptoms of a rare but serious and potentially life-threatening infection called necrotising fasciitis of the perineum (Fournier's gangrene) and you will require prompt treatment. Your doctor may tell you to stop taking QTERN.
- severe upper stomach pain, often with nausea and vomiting.
- diabetic ketoacidosis. In rare cases dapagliflozin, one of the active ingredients in QTERN, may cause a serious side effect called diabetic ketoacidosis. Seek immediate medical attention when symptoms such as nausea, vomiting, decreased appetite, abdominal pain, excessive thirst, difficulty in breathing, confusion, unusual fatigue or sleepiness, frequent urination, fruity-smelling breath, rapid weight loss, sweet or metallic taste in your mouth, and different odour to your urine and sweat occur. 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.

- signs and symptoms of heart failure. Signs of heart failure may include, increasing shortness of breath, rapid increase in weight and swelling of the feet.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Occasionally, QTERN may be associated with changes in your blood. These can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed here may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of QTERN

- *Storage*

Keep your QTERN tablets in the blister until it is time to take them. If you take QTERN out of the blister it will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store QTERN or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill. Heat and dampness can destroy some

medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

If your doctor tells you to stop taking QTERN or the tablets have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

- What it looks like

QTERN 5 mg/10 mg film-coated tablets are light brown to brown, biconvex, round, with “5/10” printed on one side, and “1122” printed on the other side, in blue ink. Available in blister packs of 28 tablets.

- Ingredients

Active ingredient(s)

Each QTERN 5 mg/10 mg film-coated tablet contains the following active ingredients:

- saxagliptin 5 mg and
- dapagliflozin 10 mg

Inactive ingredients

Each QTERN 5 mg/10 mg film-coated tablet contains the following inactive ingredients:

- microcrystalline cellulose
- lactose
- croscarmellose sodium
- silicon dioxide
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide
- macrogol 3350
- talc
- red iron oxide
- yellow iron oxide
- OPACODE ink S-1-10619 Blue

QTERN tablets do not contain gluten or sucrose.

- MAL number

MAL19016095ARZ

Manufacturer

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Product Registration Holder

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