

Package leaflet: Information for the patient

Qtern 5 mg/10 mg film-coated tablets

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

1. What Qtern is and what it 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 diabetes.
- This medicine is used if your diabetes cannot be controlled with other oral diabetes medicines, along with diet and exercise.

Qtern is used for a type of diabetes called “type 2 diabetes mellitus” in adult patients (aged 18 years and older). “Type 2 diabetes mellitus” is the type of diabetes that usually starts when you are older. If you have type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use the insulin it produces properly. This leads to a high level of sugar in your blood. The two active substances in Qtern work in different ways to help control the level of sugar in your blood and remove excess sugar from your body via your urine.

It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

2. What you need to know before you take Qtern

Do not take Qtern:

- if you are allergic to saxagliptin, dapagliflozin or any of the other ingredients of this medicine (listed in section 6).

- if you have had a serious allergic reaction to any other similar medicines (for example DPP-4 inhibitors like sitagliptin, linagliptin, alogliptin, or SGLT2 inhibitors like canagliflozin, empagliflozin) that you take to control your blood sugar.

Do not take Qtern if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist, or nurse before taking Qtern.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Qtern, and during treatment:

- 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 or have had a disease of the pancreas.
- if you have reduced kidney function.
- if you have a condition that reduces your body’s ability to fight infections, such as a disease like AIDS or from medicines that you might take after an organ transplant.
- if you have moderate or severe liver problem.
- if you experience rapid weight loss, 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, contact a doctor or the nearest hospital straight away. These 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.
- if you have or have had a serious hypersensitivity reaction or is suspected.
- if you have a history of serious heart disease.
- if you suffer from heart failure or you have other risk factors for developing heart failure such as problems with your kidneys. Your doctor will advise you of the signs and symptoms of heart failure. Symptoms can include, but are not limited to, increasing shortness of breath, rapid increase in weight and swelling of the feet (pedal oedema). You should call your doctor, pharmacist or nurse immediately if you experience any of these symptoms.
- if you are on medicines to lower your blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). For more information, see section “Other medicines and Qtern” below.
- 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 at the top of section 4. Tell your doctor before you start taking Qtern 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 Qtern until you recover to prevent dehydration.
- if you often get infections of the urinary tract or have a serious infection of the urinary tract, including urosepsis or pyelonephritis, which can cause fever and/or chills, burning sensation when passing water (urinating), blood in urine, pain in your back or side. You should call your doctor, pharmacist or nurse immediately if you experience any of these symptoms.
- if you are 75 years old or older.
- if you are taking a medicine to lower your blood sugar, such as insulin or sulphonylureas.
- if you are taking another medicine for diabetes that contains “pioglitazone”.
- if you have an increase in the amount of red blood cells in your blood, seen in tests.

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

Diabetic skin lesions (skin damage such as sores or ulcers) are a common complication of diabetes. Rash has been seen with both saxagliptin and dapagliflozin when given separately (see section 4). You are advised to follow the recommendations for skin care that you are given by your doctor or nurse. Contact your doctor if you encounter blistering of the skin, as it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop Qtern.

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

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.

Kidney function

Your kidneys should be checked before you start taking and whilst you are on this medicine.

Urine tests

Because of how Qtern works, your urine will test positive for sugar while you are on this medicine.

Children and adolescents

Qtern is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

Other medicines and Qtern

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 increase the amount of water you pass out of the body (diuretic). Your doctor may ask you to stop taking Qtern. Possible signs of losing too much fluid from your body are listed at the top of section 4.
- if you are using medicines containing any of the following active substances:
 - Carbamazepine, phenobarbital or phenytoin. These may be used to control fits (seizures) or chronic pain.
 - Dexamethasone – a steroid medicine. This may be used to treat inflammation in different body parts and organs.
 - Rifampicin. This is an antibiotic used to treat infections such as tuberculosis.
 - Ketoconazole. This may be used to treat fungal infections.
 - Diltiazem. This is a medicine used to treat angina (chest pain) and lower blood pressure.

If any of the above apply to you (or if you are not sure), talk to your doctor before taking Qtern.

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. Qtern is not recommended during pregnancy and your doctor will ask you to stop taking this medicine if you become pregnant. Talk to your doctor about the best way to control your blood sugar while you are pregnant.

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

Driving and using machines

Qtern is not expected to affect you being able to drive a car or use any tools or machines. If you feel dizzy while taking Qtern, do not drive or use any tools or machines. Taking this medicine can cause blood sugar levels to fall too low (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines.

Qtern contains lactose

Qtern 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.

Sodium content

Qtern contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially 'sodium-free'.

3. How to take Qtern

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 tablet a day.

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 other medicines to lower the amount of sugar in your blood. Remember to take other medicine(s) as your doctor has told you. This will help get the best results for your health.

Diet and exercise

To control your diabetes, you still need to keep to diet and exercise, even when you are taking this medicine. So it is important to keep following the advice about diet and exercise from your doctor, pharmacist or nurse. In particular, if you are following a diabetic weight control diet, continue to follow it while you are taking Qtern.

If you take more Qtern than you should

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

If you forget to take Qtern

What to do if you forget to take a tablet.

- If it is less than 12 hours since you should have taken your dose, take a dose of Qtern as soon as you remember. Then take your next dose at the usual time.
- If it is more than 12 hours since you should have taken your dose, skip the missed dose. Then take your next dose at the usual time.
- Do not take a double dose of Qtern to make up for a forgotten dose.

If you stop taking Qtern

Do not stop taking Qtern without talking to your doctor first. 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.

Some symptoms need immediate medical attention:

Stop taking Qtern and see a doctor straight away if you notice any of the following serious side effects:

- Symptoms of a serious allergic reaction seen rarely, (may affect up to 1 in 1,000 people), which may include:
 - Rash
 - Raised red patches on your skin (hives)
 - Swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.

Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

- **Pancreatitis**, seen uncommonly (may affect up to 1 in 100 people): severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas.
- **Dehydration, (loss of too much fluid from your body)**, seen uncommonly (may affect up to 1 in 100 people).
These are signs of dehydration:
 - very dry or sticky mouth, feeling very thirsty
 - feeling very sleepy or tired
 - passing little or no water (urine)
 - fast heart beat.
- **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.

- **Low blood sugar levels (hypoglycaemia)**, seen very commonly (may affect more than 1 in 10 people) if used with other diabetes medicines known to cause hypoglycaemia.

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.

- **Diabetic ketoacidosis**, seen rarely (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
- rapid weight loss
- 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.

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

- **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 (may affect up to 1 in 10,000 people).

Stop taking Qtern and see a doctor or nurse straight away, if you notice any of the serious side effects above.

Other side effects when taking Qtern alone or in combination with metformin:

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)
- dizziness
- tiredness
- stomach ache

- severe joint pain (arthralgia)
- infection of the upper chest or lungs
- infection of the sinuses with a feeling of pain and fullness behind your cheeks and eyes (sinusitis)
- inflamed nose or throat (nasopharyngitis) (signs of this may include a cold or a sore throat)
- stomach ache and indigestion (dyspepsia)
- nausea
- diarrhoea
- inflamed stomach or gut usually caused by an infection (gastroenteritis)
- headache, muscle pain (myalgia)
- vomiting, inflammation of the stomach (gastritis)
- changes in laboratory tests (for example creatinine renal clearance decreased or haematocrit increased)
- rash.

Uncommon

- thirst
- constipation
- awakening from sleep at night to pass urine
- dry mouth
- weight decreased
- increases in creatinine or urea (shown in laboratory blood tests)
- decrease in kidney function
- skin rash that may include raised bumps, skin irritation, or unpleasant itchiness
- difficulties in getting or maintaining an erection (erectile dysfunction)
- fungal infection
- hypersensitivity reactions
- itching in the genital area (pruritus genital or vulvovaginal pruritus) or discomfort while urinating.

Not known (frequency cannot be estimated from the available data)

- blistering of the skin (bullous pemphigoid)

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Qtern

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 to protect the environment.

6. Contents of the pack and other information

What Qtern contains

- The active substances are saxagliptin and dapagliflozin.
- Each tablet contains saxagliptin hydrochloride equivalent to 5 mg saxagliptin and dapagliflozin propanediol monohydrate equivalent to 10 mg dapagliflozin.
- The other ingredients are:
 - tablet core: microcrystalline cellulose (E460i), croscarmellose sodium (E468) (see section 2 ‘Sodium content’), anhydrous lactose (see section 2 ‘Qtern contains lactose’), magnesium stearate (E470b), dental type silica (E551).
 - film-coating: polyvinyl alcohol (E1203), macrogol 3350, titanium dioxide (E171), talc (E553b), yellow iron oxide (E172), red iron oxide (E172).
 - printing ink: shellac, indigo carmine aluminium lake (E132).

What Qtern looks like and contents of the pack

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

Qtern 5 mg/10 mg tablets are available in aluminium blisters in pack sizes of 14, 28, or 98 film-coated tablets in calendar blisters and 30 film-coated tablets in blister.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

AstraZeneca AB
SE-151 85 Södertälje
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Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>

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