

**Package leaflet: Information for the patient**  
**Xigduo® 5 mg/1,000 mg film-coated tablets**  
(dapagliflozin/metformin hydrochloride)

**Your medicine is known as the above but will be referred to as Xigduo throughout the remainder of this leaflet.**

**Your medicine is available in multiple strengths and all strengths will be referred to throughout the remainder of this leaflet.**

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

**1. What Xigduo is and what it is used for**

This medicine contains two different substances called dapagliflozin and metformin. Both belong to a group of medicines called oral anti-diabetics. These are medicines taken by mouth for diabetes.

Xigduo is used for a type of diabetes called “type 2 diabetes” in adult patients (aged 18 years and older) and usually occurs 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 (glucose) in your blood.

- Dapagliflozin works by removing excess sugar from your body via your urine and lowers the amount of sugar in your blood. It can also help prevent heart disease.
- Metformin works mainly by inhibiting glucose production in the liver.

To treat diabetes:

- This medicine is taken in combination with diet and exercise.
- This medicine is used if your diabetes cannot be controlled with other medicines used to treat diabetes.
- Your doctor may ask you to take this medicine on its own or together with other medicines to treat diabetes. This may be another medicine taken by mouth and/or a medicine given by injection, such as insulin or a GLP-1 receptor agonist (helps your body to increase the production of insulin when your blood sugar is high).
- If you are already taking both dapagliflozin and metformin as single tablets, your doctor may ask you to switch to this medicine. To avoid overdose, do not continue taking dapagliflozin and metformin tablets, if you are taking Xigduo.

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 Xigduo**

**Do not take Xigduo**

- if you are allergic to dapagliflozin, metformin or any of the other ingredients of this medicine (listed in section 6).
  - if you have ever had a diabetic coma.
  - if you have uncontrolled diabetes, with, for example severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see “Risk of lactic acidosis” below) or ketoacidosis. Ketoacidosis is a condition in which substances called ‘ketone bodies’ accumulate in the blood and which can lead to a diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.
  - if you have severely reduced kidney function.
  - if you have a severe infection.
  - if you have lost a lot of water from your body (dehydration), e.g. due to long-lasting or severe diarrhoea, or if you have vomited several times in a row.
  - if you have recently had a heart attack or if you have heart failure or serious problems with your blood circulation or difficulties in breathing.
  - if you have problems with your liver.
  - if you drink large amounts of alcohol, either every day or only from time to time (please see section “Xigduo with alcohol”).
- Do not take this medicine if any of the above apply to you.

**Warnings and precautions**

**Risk of lactic acidosis**

Xigduo may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

**Stop taking Xigduo for a short time if you have a condition that may be associated with dehydration** (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

**Stop taking Xigduo and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis**, as this condition may lead to coma.

Symptoms of lactic acidosis include:

- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

**Talk to your doctor promptly for further instructions:**

- if you are known to suffer from a genetically inherited disease affecting mitochondria (the energy producing components within cells) such as MELAS syndrome (Mitochondrial Encephalomyopathy with Lactic acidosis, and Stroke-like episodes) or Maternally Inherited Diabetes and Deafness (MIDD).
- if you have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

**Talk to your doctor, pharmacist or nurse before taking Xigduo, 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. Xigduo should not be used to treat this condition.
- 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 problems with your kidneys. Your doctor will check your kidney function.
- if you have very high levels of glucose 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 this medicine if you have any of these signs.
- if you are taking medicines to lower blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). More information is given below under ‘Other medicines and Xigduo’.
- if you often get infections of the urinary tract. This medicine may cause urinary tract infections and your doctor may want to monitor you more closely. Your doctor may consider temporarily changing your treatment if you develop a serious infection.

If you need to have major surgery, you must stop taking Xigduo during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Xigduo.

It is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.

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

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**

During treatment with Xigduo, your doctor will check your kidney function at least once every year or more frequently if you are elderly and/or if you have worsening kidney function.

**Urine glucose**

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

**Children and adolescents**

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

**Other medicines and Xigduo**

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop taking Xigduo before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Xigduo.

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may adjust the dosage of Xigduo. It is especially important to mention the following:

- if you are taking medicines which increase urine production (diuretics). Your doctor may ask you to stop taking this medicine. Possible signs of losing too much fluid from your body are listed at the top of section 4.
- 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 blood sugar levels that are too low (hypoglycaemia).
- if you are taking cimetidine, a medicine used to treat stomach problems.
- if you are using bronchodilators (beta-2 agonists) which are used to treat asthma.
- if you are using corticosteroids (used to treat inflammation in diseases like asthma and arthritis) that are given by mouth, as an injection, or inhaled.
- if you are using medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- if you are using certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).

**Xigduo with alcohol**

Avoid excessive alcohol intake while taking Xigduo since this may increase the risk of lactic acidosis (see “Warnings and precautions”).

**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 (the last six months) 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. You should not use this medicine if you are breast-feeding.

Metformin passes into human milk in small amounts. It is not known if dapagliflozin passes into human breast milk.

**Driving and using machines**

This medicine has no or negligible influence on the ability to drive and use machines. Taking it with other medicines that lower the amount of sugar in your blood, such as insulin or a “sulphonylurea” medicine, can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as weakness, dizziness, increased sweating, fast heart beat, change in vision or difficulties concentrating, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you start to feel these symptoms.

**Sodium content**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially ‘sodium-free’.