

- 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’.

3. How to take Xigduo

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 amount of this medicine that you will take varies depending on your condition and the doses you currently take of metformin and/or individual tablets of dapagliflozin and metformin. Your doctor will tell you exactly which strength of this medicine to take.
- The recommended dose is one tablet twice a day.

Taking this medicine

- Swallow the tablet whole with half a glass of water.
- Take your tablet with food. This is to reduce the risk of side effects in the stomach.
- Take your tablet twice daily, once in the morning (breakfast) and once in the evening (dinner).

Your doctor may prescribe this medicine together with other medicine(s) to lower the amount of sugar in your blood. These may be medicine(s) by mouth or given by injection, such as insulin or a GLP-1 receptor agonist. Remember to take these 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 this medicine.

If you take more Xigduo than you should

If you take more Xigduo tablets than you should, you may experience lactic acidosis. Symptoms of lactic acidosis include feeling or being very sick, vomiting, stomach ache, muscular cramps, severe tiredness or difficulty breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking this medicine immediately and contact a doctor or the nearest hospital straight away (see section 2). Take the medicine pack with you.

If you forget to take Xigduo

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of this medicine to make up for a forgotten dose.

If you stop taking Xigduo

Do not stop taking this medicine 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.

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

- Lactic acidosis**, seen very rarely (may affect up to 1 in 10,000 people)

Xigduo may cause a very rare, but very serious side effect called lactic acidosis (see section “Warnings and precautions”). If this happens you must **stop taking Xigduo and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

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

- 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 Xigduo.

- 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 Xigduo and see a doctor as soon as possible if you notice any of the following serious or potentially serious effects:

- 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 heartbeat.

- 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.

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) - when taking this medicine with a sulphonylurea or other medicines that lower the amount of sugar in your blood, such as 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. If you have symptoms of low blood sugar, eat glucose tablets, a high sugar snack or drink fruit juice. Measure your blood sugar if possible and rest.

Other side effects include:

Very common

- nausea, vomiting
- diarrhoea or stomach ache
- loss of appetite

Common

- decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.
- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- back pain
- discomfort when passing water (urine), passing more water 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) in the beginning of treatment
- changes in taste
- dizziness
- rash

Uncommon

- thirst
- constipation
- awakening from sleep at night to pass urine
- dry mouth
- weight decreased
- increases in creatinine (shown in laboratory blood tests) in the beginning of treatment
- increases in urea (shown in laboratory blood tests)

Very rare

- abnormalities in liver function tests, inflammation of the liver (hepatitis)
- redness of the skin (erythema), itching or an itchy rash (hives)

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.