

Xigduo XR

Pronunciation: ZIG-DO-OH X-R

Generic name: dapagliflozin and metformin

Dosage form: oral tablet

Drug class: Antidiabetic combinations

Medically reviewed by Carmen Pope, BPharm. Last updated on Jun 16, 2024.

What is Xigduo XR?

Xigduo XR extended-release tablets contain a combination of dapagliflozin and metformin. Dapagliflozin and metformin are oral diabetes medicines that help control blood sugar levels. Dapagliflozin works by helping the kidneys get rid of glucose from your bloodstream. Metformin lowers glucose production in the liver and also causes your intestines to absorb less glucose.

Xigduo XR is used together with diet and exercise to improve blood sugar control in adults and children aged 10 years and older with type 2 diabetes mellitus.

- It is not for treating type 1 diabetes.

Xigduo XR is also used to:

- lower the risk of needing to be in the hospital for heart failure in adults with type 2 diabetes who also have heart disease
- reduce the risk of worsening kidney disease and death due to heart problems, and the need to be in the hospital for heart failure in adults with type 2 diabetes who also have chronic kidney disease.

Xigduo was FDA-approved on 29 October 2014.

Xigduo XR side effects

Common Xigduo XR side effects affecting 5% or more people who take it include:

- female genital infections
- headache
- nausea, vomiting, diarrhea or
- runny or stuffy nose, or a sore throat.

Serious side effects

Xigduo XR can cause **serious side effects**.

Get emergency medical help if you have **signs of an allergic reaction to Xigduo XR**, such as hives; difficulty breathing; or swelling of your face, lips, tongue, or throat.

Seek medical attention right away if you have signs of a genital infection (penis or vagina): burning, itching, odor, discharge, pain, tenderness, redness or swelling of the genital or rectal area, fever, not feeling well. **These symptoms may get worse quickly.**

Xigduo XR can cause some people to become **dehydrated** (the loss of body water and salt). This may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). There have been reports of sudden kidney injury in people with type 2 diabetes mellitus who are taking dapagliflozin, a medicine in Xigduo XR. You may be at a higher risk of dehydration if you:

- take medicines to lower your blood pressure, including water pills (diuretics)
- are on a low-salt diet
- have kidney problems
- are 65 years of age or older.

Talk to your healthcare provider about what you can do to prevent dehydration including how much fluid you should drink daily. Call your healthcare provider right away if you reduce the amount of food or liquid you drink, for example, if you cannot eat or you start to lose liquids from your body, for example from vomiting, diarrhea, or being in the sun too long.


Call your doctor at once if you have:

- little or no urination;
- **signs of a bladder infection** - pain or burning when you urinate, increased urination, blood in your urine, fever, pain in your pelvis or back;
- **dehydration symptoms** - dizziness, weakness, feeling light-headed (like you might pass out);
- **ketoacidosis (too much acid in the blood)** - nausea, vomiting, stomach pain, confusion, unusual drowsiness, or trouble breathing; or
- **lactic acidosis** - unusual muscle pain, trouble breathing, stomach pain, vomiting, irregular heart rate, dizziness, feeling cold, or feeling very weak or tired

Side effects may be more likely to occur in adults aged 65 years and older.

Other serious side effects of Xigduo XR include vitamin B12 deficiency with long-term use.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 Xigduo XR side effects (more detail)

Related/similar drugs

Ozempic

Learn about Ozempic (semaglutide) for type 2 diabetes treatment, weight management, cardiovascular ...

Reviews & ratings

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Rybelsus

Rybelsus tablets are used to improve blood sugar control in adults with type 2 diabetes, and may ...

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Mounjaro

Mounjaro is used to improve blood sugar control in adults with type 2 diabetes, and may ...

Review

8.6 / 10

Warnings

You should not use Xigduo XR if you have severe kidney disease or diabetic ketoacidosis (seek emergency medical treatment).

If you need to have any type of X-ray or CT scan using a dye that is injected into your veins, you may need to temporarily stop taking Xigduo XR.

You may develop **lactic acidosis**, a dangerous build-up of lactic acid in your blood. Call your doctor or get emergency medical help if you have unusual muscle pain, trouble breathing, stomach pain, dizziness, feeling cold, or feeling very weak or tired.

In rare cases, this medicine can cause serious infections in the penis or vagina. Get medical help right away if you have burning, itching, odor, discharge, pain, tenderness, redness or swelling of the genital or rectal area, fever, or if you don't feel well.

Before taking this medicine

You should not use Xigduo XR if you are allergic to dapagliflozin (Farxiga) or metformin, or if you have:

- severe kidney disease (or if you are on dialysis); or
- metabolic acidosis or diabetic ketoacidosis (call your doctor for treatment).

Before starting Xigduo XR you should be well hydrated.

To make sure Xigduo XR is safe for you, tell your doctor if you have ever had:

- liver or kidney disease

- a serious infection
- low blood pressure
- a bladder infection or urination problems
- heart problems, low blood pressure
- problems with your pancreas, including surgery or
- if you are on a low-salt diet
- take diuretics (fluid pills) or other medications such as insulin that lower blood sugar levels history of infection of the vagina or penis
- are pregnant or intending to become pregnant
- are breastfeeding.

You may develop **lactic acidosis**, a dangerous build-up of lactic acid in your blood. This may be more likely if you have other medical conditions, a severe infection, chronic alcoholism, or if you are 65 or older. Ask your doctor about your risk.

Your doctor may perform kidney function tests before you start taking Xigduo XR.

Xigduo XR is not approved for use by anyone younger than 18 years old.

Pregnancy

Xigduo XR may cause harm to the developing kidneys of an unborn baby and is not recommended during the second or third trimester of pregnancy. Follow your doctor's instructions about using Xigduo XR if you are pregnant or you become pregnant. Blood sugar control is very important during pregnancy, and your dose needs may be different during each trimester.

Tell your doctor right away if you become pregnant.

Xigduo XR contains metformin which may stimulate ovulation in a premenopausal woman and may increase the risk of unintended pregnancy. Talk to your doctor about your risk.

Breastfeeding

You should not breastfeed while using Xigduo XR.

 Xigduo XR pregnancy and breastfeeding warnings (more detail)

How should I take Xigduo XR?

Take Xigduo XR extended-release tablets exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may

occasionally change your dose.

- Xigduo XR is usually taken once daily, in the morning.
- Take with food to prevent an upset stomach.
- Swallow the tablet whole. Do not crush, chew, or break the extended-release tablet.

You may have low blood sugar (**hypoglycemia**) and feel very hungry, dizzy, irritable, confused, anxious, or shaky. To quickly treat hypoglycemia, eat or drink a fast-acting source of sugar (fruit juice, hard candy, crackers, raisins, or non-diet soda).

- Your doctor may prescribe a glucagon injection kit in case you have severe hypoglycemia. Be sure your family or close friends know how to give you this injection in an emergency.
- Also, watch for signs of high blood sugar (hyperglycemia) such as increased thirst or urination.
- Blood sugar levels can be affected by stress, illness, surgery, exercise, alcohol use, or skipping meals. **Ask your doctor before changing your dose or medication schedule.**

Call your doctor if you have ongoing vomiting or diarrhea, or if you are sweating more than usual. You can easily become dehydrated while taking this medicine, which can lead to severely low blood pressure or a serious electrolyte imbalance.

If you need surgery or medical tests, tell any doctor who treats you that you are using Xigduo XR.

This medicine is only part of a treatment program that may also include diet, exercise, weight control, blood sugar testing, and special medical care. Follow your doctor's instructions very closely.

Your doctor may have you take extra vitamin B12 while you are taking Xigduo XR. Take only the amount of vitamin B12 that your doctor has prescribed.

Xigduo XR dosing information

Recommended Xigduo XR dose for adults and children aged 10 and older for Type 2 diabetes to improve blood sugar control

- Initial dose: 5 mg once daily.
 - This is based on the dapagliflozin component. The metformin component should be individualized to the patient, and the corresponding tablet prescribed (the possible dose range for the metformin component ranges from 500 mg to 2000 mg).
- May increase to 10 mg orally once a day (dapagliflozin component) for additional glycemic control if a lower dose has been tolerated
- Maximum dose: dapagliflozin 10 mg-metformin 2000 mg per day.

Usual adult dose for other indications

- Initial and maintenance dose: 10 mg orally once a day
 - This is based on the dapagliflozin component. The metformin component should be individualized to the patient, and the corresponding tablet prescribed (the possible dose range for the metformin component ranges from 500 mg to 2000 mg).
- Maximum dose: dapagliflozin 10 mg-metformin 2000 mg per day.

Comments

- Patients taking an evening dose of metformin should skip their last dose before starting this drug; take this drug once daily in the morning with food.
- When used in combination with insulin or insulin secretagogue, a lower dose of insulin or insulin secretagogue may be considered to reduce the risk of hypoglycemia.

 Detailed Xigduo XR dosage information

Should Xigduo XR be stopped for surgery?

The Package Insert recommends withholding Xigduo XR for at least 3 days, if possible, before major surgery or procedures associated with prolonged fasting. Xigduo XR should be restarted once the person is clinically stable and has started eating or receiving nutrition again.

What happens if I miss a dose?

Take the medicine (with food) as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. You may have severely low blood sugar (extreme weakness, nausea, tremors, sweating, confusion, trouble speaking, fast heartbeats, or seizures).

What to avoid

Avoid drinking alcohol often or drinking a lot of alcohol in a short period ("binge" drinking). It can increase your chances of getting serious side effects.

Avoid getting up too fast from a sitting or lying position, or you may feel dizzy.

Avoid becoming dehydrated. Keep up your fluid intake during hot weather or exercise.

What other drugs will affect Xigduo XR?

Tell your doctor about all your other medicines, especially:

- digoxin (digitalis, Lanoxin);
- rifampin;
- phenytoin;
- a diuretic or "water pill";
- insulin or other oral diabetes medications; or
- **NSAIDs (nonsteroidal anti-inflammatory drugs)** - aspirin, ibuprofen (Advil, Motrin), naproxen (Aleve), celecoxib, diclofenac, indomethacin, meloxicam, and others.

This list is not complete. Other drugs may interact with dapagliflozin and metformin, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

 Xigduo XR drug interactions (more detail)

Storage

Store at room temperature, away from moisture and heat.

Keep out of reach of children.

Ingredients

Active ingredients: dapagliflozin and metformin hydrochloride

Inactive ingredients: anhydrous lactose, carboxymethylcellulose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, and silicon dioxide.

Film coatings: polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide. FD&C Yellow No. 6/Sunset

Yellow FCF aluminum lake (Xigduo XR 5 mg/500 mg). Iron oxides (Xigduo XR 2.5 mg/1000 mg, 5 mg/1000 mg, 10 mg/500 mg, and 10 mg/1000 mg).

Manufacturer

AstraZeneca Pharmaceuticals LP.

Frequently asked questions

- What are the ingredient drugs contained in Qternmet XR?

References

1. Xigduo XR Package Insert

Was this page helpful?



Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.