

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **XIGDUO®**

dapagliflozin and metformin hydrochloride tablets

This Patient Medication Information is written for the person who will be taking **XIGDUO**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **XIGDUO**, talk to a healthcare professional.

Serious warnings and precautions box

Lactic Acidosis:

- **XIGDUO** contains metformin and may cause lactic acidosis. This is a serious condition when there is too much lactic acid in your body. It can cause death. The risk of lactic acidosis is higher if you:
 - have liver, kidney or heart problems, including heart failure.
 - drink a lot of alcohol. Do not drink a lot of alcohol while taking **XIGDUO**.
 - are 80 years of age or older.
- **Stop taking XIGDUO right away** and talk to your healthcare professional if you have any of the following symptoms:
 - discomfort, difficulty breathing, nausea, vomiting, diarrhea, stomach or muscle pain, extreme tiredness, weakness, feeling cold, low blood pressure or slow or irregular heartbeat
- **XIGDUO** can also cause diarrhea, nausea, upset stomach, bloating, gas or loss of appetite. If any of these side effects come back after you are on the same dose of **XIGDUO** for many days or weeks, tell your healthcare professional right away. These symptoms may be due to lactic acidosis.
- Lactic acidosis must be treated in the hospital. Your healthcare professional will decide the best treatment options for you.

Diabetic Ketoacidosis:

- Diabetic ketoacidosis (DKA) can happen while you are taking **XIGDUO**. It is a serious and life-threatening condition, which may need urgent hospital care. Some cases of DKA have led to death. DKA can happen to diabetic patients with normal or high blood sugar levels.
- In DKA your body produces high levels of blood acids called ketones. It occurs because your body does not have enough insulin.
- Seek medical help and **stop taking XIGDUO right away** if you have any of the following symptoms (even if your blood sugar levels are normal):
 - difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusually tired, a sweet smell to the breath, a sweet or

metallic taste in the mouth, or a different odour to urine or sweat.

- Do not use XIGDUO if you have:
 - DKA or a history of DKA
 - type 1 diabetes

What XIGDUO is used for:

XIGDUO is used along with diet and exercise to:

- control blood sugar levels in adults with type 2 diabetes. XIGDUO can be used in patients taking:
 - dapagliflozin and metformin as separate tablets, or
 - dapagliflozin, metformin and a sulfonylurea, or
 - dapagliflozin, metformin and sitagliptin, or
 - dapagliflozin, metformin and insulin.

How XIGDUO works:

XIGDUO contains dapagliflozin and metformin hydrochloride.

- Dapagliflozin removes excess sugar from the body through the urine.
- Metformin helps your body respond better to the insulin it makes naturally. It helps to lower the amount of sugar made by the liver and lower the amount of sugar moved from the gut into the blood.

The ingredients in XIGDUO are:

Medicinal ingredients: dapagliflozin (as dapagliflozin propanediol monohydrate) and metformin hydrochloride.

Non-medicinal ingredients: cellulose microcrystalline, hydroxypropylcellulose, iron oxide red, iron oxide yellow, macrogol/polyethylene glycol, magnesium stearate (extragranular), polyvinyl alcohol, sodium starch glycolate, talc and titanium dioxide.

XIGDUO comes in the following dosage form:

Tablet:

- 5 mg dapagliflozin (as dapagliflozin propanediol monohydrate) / 850 mg metformin hydrochloride
- 5 mg dapagliflozin (as dapagliflozin propanediol monohydrate) / 1000 mg metformin hydrochloride

Do not use XIGDUO if:

- you have unstable and/or insulin-dependent (type 1) diabetes mellitus
- you have or have a history of metabolic acidosis (including diabetic ketoacidosis / DKA or ketoacidosis, with or without coma)
- you have a history of lactic acidosis (too much acid in the blood)
- you have or ever had severe kidney or liver problems, or are on dialysis
- you regularly drink large amounts of alcohol all the time or short-term 'binge'
- you are going to get an injection of dyes (iodinated contrast materials) for medical imaging
- you have severe problems with your blood circulation or heart problems that can cause hypoxemia (low oxygen in the blood)
- you are stressed and have a severe infection, or are experiencing trauma
- you will have surgery or are recovering from surgery

- you suffer from severe dehydration (have lost a lot of water from your body) or shock
- you are allergic (hypersensitive) to dapagliflozin, metformin hydrochloride or any of the ingredients listed in this medicine or component of the container
- you are pregnant or planning to become pregnant
- you are breastfeeding or plan to breastfeed

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take XIGDUO. Talk about any health conditions or problems you may have, including if you:

- have an increased risk of developing DKA, including if you:
 - are dehydrated or suffer from excessive vomiting, diarrhea, or sweating
 - are on a very low carbohydrate diet
 - have been fasting for a while
 - need to have a procedure that requires long periods of fasting
 - are eating less, or there is a change in your diet
 - drink a lot of alcohol
 - have/have had problems with your pancreas, including pancreatitis or surgery on your pancreas
 - are or going to be hospitalized for major surgery, serious infection or serious medical illnesses. Your healthcare professional may stop your treatment with XIGDUO. Talk to your healthcare professional about when to stop taking XIGDUO and when to start taking it again.
 - have a sudden reduction in your insulin dose
 - have a history of DKA
- are older than 65 years of age
- have a history or had liver or kidney problems
- have stomach problems
- have hormone problems (adrenal (found on top of your kidneys) or pituitary glands (found in your brain))
- have low blood sugar
- have low vitamin B₁₂ or folic acid levels
- have low blood pressure
- have or had heart problems (like heart failure, heart attack or heart disease)
- are taking medicines to lower your blood pressure, including diuretics, known as water pills. If you take XIGDUO with these medicines, it can increase the risk of dehydration.
- are taking medicines to lower blood sugar. Taking XIGDUO with any of these medications can increase the risk of having low blood sugar (hypoglycemia).
- have a history of yeast infection of the vagina or penis
- have a history of urinary tract infections
- have had a recent stroke
- are dehydrated
- are scheduled for x-ray or scanning procedures
- are 80 years of age or older and have NOT had your kidney function tested
- have had an allergic reaction to other medicines used to treat type 2 diabetes
- have or think you have certain mitochondrial diseases, specifically Mitochondrial Encephalomyopathy with Lactic Acidosis, and Stroke-like episodes (MELAS) syndrome and Maternally Inherited Diabetes and Deafness (MIDD) (diseases that are passed down at birth affecting mitochondria). For these patients, taking XIGDUO increases the risk for lactic acidosis and can lead to worsening of the mitochondrial disease

Other warnings you should know about:

XIGDUO can cause serious side effects, including:

- **Vitamin B₁₂ levels:** XIGDUO can cause your vitamin B₁₂ levels to be lower. This could cause peripheral neuropathy (nerve damage) or anemia (low red blood cells).
- **Hypoglycemia (low blood sugar):** XIGDUO rarely causes hypoglycemia (low blood sugar) by itself. Hypoglycemia can happen if you:
 - take other medicines to lower blood sugar. Your healthcare professional may adjust your dose of insulin or other antidiabetic medicines when taking XIGDUO. This is to help you keep your blood sugar levels within the normal range during your treatment.
 - do not eat enough
 - drink alcohol
 - have hormone (adrenal or pituitary gland) or liver problems
- **Thyroid problems (hypothyroidism):** tell your healthcare professional if you have thyroid problems or if you are being treated with levothyroxine (a drug used to treat thyroid problems). Your healthcare professional will monitor your thyroid health.
- **Yeast infection:** XIGDUO increases your risk of getting a yeast infection of the vagina or penis, especially if you have had them in the past.
- **Urinary tract infection, including urosepsis:** Urosepsis is a severe infection that spreads from the urinary tract throughout the body. This condition is serious and may be life-threatening if left untreated. If you experience signs of this condition, stop taking XIGDUO right away and seek immediate medical help.
- **Fournier's gangrene:** This is a serious infection affecting the soft tissue around the groin. Rare cases of Fournier's gangrene have been reported in patients with type 2 diabetes while taking SGLT2 inhibitors like XIGDUO. This condition is serious and may be life threatening. If you experience signs of this condition, stop taking XIGDUO right away and seek immediate medical help.

See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

Pregnancy and breastfeeding:

- Do not take XIGDUO if you are pregnant.
- Tell your healthcare professional right away if you plan to become pregnant or think you may be pregnant during your treatment with XIGDUO. It is not known if XIGDUO will harm your unborn baby.
- Do not breastfeed while you are taking XIGDUO. It is not known if XIGDUO will pass into your breast milk. Talk to your healthcare professional if you would like to breastfeed.

Children and adolescents: XIGDUO is not to be used in children and adolescents under 18 years of age.

Patients older than 65 years old: You should not take XIGDUO if you are older than 80 years old unless certain tests are done to check your kidney health. XIGDUO should be used with

care as age increases because older patients are more likely to have kidney problems. Your healthcare professional may do certain tests to check your kidney health.

Driving and using machines: Before doing tasks that require special attention, wait until you know how you respond to XIGDUO. Dizziness, light-headedness or fainting can happen, particularly when XIGDUO is taken with insulin or other antidiabetic medicines.

Worsening of existing mitochondrial disease such as MELAS syndrome and MIDD: Tell your healthcare professional if you experience symptoms such as seizures, reduction in mental abilities (memory lapses, difficulty concentrating, trouble finding words or following conversations, poor judgement or decision-making), difficulty with body movements, muscle pain or weakness, pain, numbness, migraine or deafness after starting XIGDUO. These may be signs that your existing medical condition is getting worse.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XIGDUO:

- Medicines used to treat diabetes (lower blood sugar levels), like glyburide, glimepiride or glimepiride, or insulin. If you take XIGDUO with any of these medicines, it can increase the risk of low blood sugar.
- Nifedipine, ACE-inhibitors like enalapril, lisinopril and quinapril used to treat high blood pressure, chest pain and Raynaud's phenomenon
- Lithium, used to treat bipolar disorder
- Medicines used to treat irregular heartbeats like procainamide, quinidine
- Medicines used to treat heart failure and irregular heartbeats like digoxin
- Medicines used to treat pain like morphine and NSAIDs (nonsteroidal anti-inflammatory drugs)
- Medicines used to lower stomach acid like ranitidine and cimetidine
- Medicine used to treat malaria like quinine
- Medicines used to treat bacterial infections (antibiotics) like trimethoprim, vancomycin
- Medicines used as "blood thinners" like phenprocoumon or other Vitamin K anticoagulants
- Medicines used to lower the extra fluid in your body (diuretics / water pills), like furosemide, amiloride, triamterene
- Other drugs that tend to produce high blood sugar (hyperglycemia) and may lead to a loss of blood sugar control. Examples include:
 - Thiazide and other diuretics (used to lower extra fluid in your body)
 - Phenytoin, used to treat epilepsy
 - Nicotinic acid, used to prevent and treat low niacin
 - Isoniazid, used to treat tuberculosis
 - Corticosteroids (anti-inflammatory drugs) like prednisone
 - Phenothiazines, used to treat mental and emotional disorders
 - Thyroid drugs, like levothyroxine
 - Female hormones like estrogens or estrogens plus progestogen
 - Oral birth control pills
 - Sympathomimetics, used to stimulate the sympathetic nervous system
 - Medicines used to lower blood pressure, like amlodipine, felodipine, verapamil and diltiazem
 - Medicines for asthma such as salbutamol or formoterol

How to take XIGDUO:

- Take exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take by mouth with a meal. Swallow tablets whole with a glass of water.
- Do not crush or break tablets.

Your healthcare professional may temporarily stop your XIGDUO treatment:

- for at least 3 days before, and a period of time after, certain types of surgery, or procedures associated with long periods of fasting.
- when you are hospitalized for a serious infection or illness.

If XIGDUO is stopped, your healthcare professional will:

- continue to monitor for signs or symptoms of DKA.
- tell you when to start taking XIGDUO again.

Usual dose:

- **Adults 18 years and older:** Your healthcare professional will decide on the best dosage for you based on your condition.
- Your healthcare professional may lower your dose, stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if you:
 - experience serious side effects, or
 - your disease gets worse.

Overdose:

If you think you, or a person you are caring for, have taken too much XIGDUO, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

If you have taken more XIGDUO than you should have, you may get lactic acidosis. Symptoms include: rapid or trouble breathing, stomach pain, nausea and vomiting. These are followed by diarrhea, drowsiness, weakness, dizziness or headache.

Missed dose:

If you miss a dose of XIGDUO, wait for the next dose at the usual time. Do not take a double dose.

Possible side effects from using XIGDUO:

These are not all the possible side effects you may have when taking XIGDUO. If you experience any side effects not listed here, tell your healthcare professional.

- sore throat, cough
- the flu (fever, tiredness, body aches)
- stuffy or runny nose
- constipation, bloating, gas
- loss of appetite
- weight loss
- metallic taste

- diarrhea
- upset stomach
- nausea, vomiting
- back, joint or abdominal pain
- pain in the arms, legs, hands or feet
- headache
- skin problems: skin reaction, rash, itchy skin
- low vitamin B₁₂ (vitamin B₁₂ deficiency)

XIGDUO can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and interpret the results. They may check your blood fat and red blood cell levels in your blood. They may also check your liver, kidney and thyroid health.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Urinary tract infection: Pain, or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong-smelling urine, cloudy urine		✓	
Yeast infection of penis: Red, swollen, itchy head of penis; thick, lumpy discharge under foreskin; unpleasant odour; difficulty retracting foreskin; pain passing urine or during sex	✓		
Yeast infection of vagina: Severe itching, burning, soreness, irritation, and a whitish or whitish-gray cottage cheese-like discharge	✓		
Uncommon			
Hypoglycemia (low blood sugar): Shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood		✓	
Hypotension (low blood pressure): Dizziness, fainting, light-headedness; may occur when you go from lying to sitting to standing up		✓	
Volume depletion (loss of needed fluids from the body; dehydration): Dry or sticky mouth, headache, dizziness or urinating less often than normal		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Rare			
Diabetic ketoacidosis (DKA): Difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusual tiredness, a sweet smell to the breath, a sweet or metallic taste in the mouth or a different odour to urine or sweat			✓
Encephalopathy (disease of the brain that severely alters thinking): Muscle weakness in one area, poor decision-making or concentration, involuntary twitching, trembling, difficulty speaking or swallowing, seizures			✓
Fournier’s gangrene (a serious infection affecting soft tissue around the groin): Pain or tenderness, redness of the skin, or swelling in the genital or perineal area, with or without fever or feeling very weak, tired, or uncomfortable			✓
Hemolytic anemia (breakdown of red blood cells): Fatigue, pale colour, rapid heartbeat, shortness of breath, dark urine, chills, and backache			✓
Kidney problems: Any change in the amount, frequency or colour (pale or dark) of urine		✓	
Lactic acidosis (high levels of acid in the blood): Feeling very weak, tired or uncomfortable, unusual muscle pain, trouble breathing, unusual or unexpected stomach discomfort, feeling cold, feeling dizzy or lightheaded, unusual fatigue and drowsiness, suddenly develop a slow or irregular heartbeat			✓
Peripheral neuropathy (a result of damage to your peripheral nerves): Gradual onset of			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
numbness, prickling or tingling in your feet or hands, which can spread upward into your legs and arms, sharp, jabbing, throbbing, freezing or burning pain, extreme sensitivity to touch, lack of coordination and falling, muscle weakness or paralysis if motor nerves are affected			
Very Rare			
Acute kidney infection: Painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul-smelling urine, blood in your urine			✓
Liver problems: Yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness		✓	
Pancreatitis (inflammation of the pancreas): Upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen		✓	
Urosepsis (severe infection that spreads from urinary tract throughout body): Fever or low body temperature, chills, rapid breathing, rapid heartbeat, pain with urination, difficulty urinating, frequent urination			✓
Unknown			
Hypothyroidism (underactive/low thyroid): Weight gain, tiredness, hair loss, muscle weakness, feeling cold, dry skin, constipation, puffy face, heavier than normal or irregular menstrual periods, enlarged thyroid gland		✓	
Photosensitivity (sensitivity to sunlight): Itchy, red skin when exposed to sunlight		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough

to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15 to 30°C).

Keep out of reach and sight of children.

If you want more information about XIGDUO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.astrazeneca.ca; or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

This leaflet was prepared by AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4.

Date of Authorization: 2026-04-01

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