

Applicant: AstraZeneca Pharmaceuticals (Pty) Ltd

Product Name: XIGDUO® XR

Module 1.3.2.1 PIL - Approved

Strength and Dosage Form: 5 mg/500 mg, 5 mg/1000 mg,
10 mg/500 mg, 10 mg/1000 mg (Tablet)

Date of approval: 12 February 2025

Registration numbers: 52/21.2/0414; 52/21.2/0415;
52/21.2/0412; 52/21.2/0413

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

Risk of metabolic acidosis

XIGDUO XR may cause a very rare, but very serious side effect called metabolic acidosis, particularly if your kidneys are not working properly. The risk of developing metabolic 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.

XIGDUO XR 5 mg/ 500 mg / XIGDUO XR 5 mg/ 1000 mg

XIGDUO XR 10 mg/ 500 mg / XIGDUO XR 10 mg/ 1000 mg

(dapagliflozin/metformin hydrochloride)

(Contains sugar – lactose 48 mg)

Read all of this leaflet carefully before you start taking XIGDUO XR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

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- XIGDUO XR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What XIGDUO XR 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 treatment of diabetes.

XIGDUO XR is used for a type of diabetes called “type 2 diabetes” in adult patients (aged 18 years and older).

Type 2 diabetes 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.

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- Dapagliflozin works by removing excess sugar from your body 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 can be controlled with a combination of dapagliflozin and metformin.
- Your doctor may ask you to take this medicine on its own or together with other medicines to treat diabetes.

2. What you need to know before you take XIGDUO XR

Do not take XIGDUO XR:

- if you are hypersensitive (allergic) to dapagliflozin, metformin or any of the other ingredients of XIGDUO XR (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, metabolic acidosis (see “Risk of metabolic acidosis” below) or metabolic acidosis. Metabolic acidosis 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.

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- if you have moderate to severe 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.
- if you are pregnant or plan to become pregnant. Talk with your doctor about the best way to control your blood sugar while you are pregnant.
- if you are breast-feeding. Talk to your doctor if you would like to breast-feed.

Warnings and precautions

Take special care with XIGDUO XR:

- 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 together could be a sign of “diabetic metabolic acidosis” – a 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 metabolic acidosis may be increased with

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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 experience 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. These symptoms together could be a sign of “metabolic acidosis” – a very rare, but very serious side effect, particularly if your kidneys are not working properly. The risk of developing metabolic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as severe heart disease).
- if you have problems with your kidneys.
- if you have very high levels of glucose in your blood which may make you dehydrated (lose too much body fluid). Possible signs of losing too much fluid from your body are listed in Section 4 “Possible Side- Effects”. 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 in the section “Taking other medicines with XIGDUO XR”.
- if you have a history of serious heart disease or if you have had a stroke.
- 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.

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- if you are 75 years old or older, you should not start taking this medicine. This is because you may be more prone to some side effects
 - if you are taking another medicine for diabetes that contains “pioglitazone”, you should not start taking this medicine.
 - if you have an increase in the amount of red blood cells in your blood, seen in blood tests.
 - if you are going to have surgery. Your doctor will decide when you must stop and when to restart your treatment with XIGDUO XR.

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

Surgical procedures

Tell your anaesthetist and surgeon that you are taking XIGDUO XR. XIGDUO XR should be temporarily suspended before any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until your doctor says so. You may require insulin before, during and after the operation.

Children and adolescents

XIGDUO XR is not recommended for children or young people under 18 years old.

Other medicines and XIGDUO XR

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Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 XR. 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 in Section 4 “Possible Side-Effects”.
- 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, which are used to treat inflammation in diseases like asthma and arthritis.
- 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).
- if you are using lithium, a medicine used to treat depression.

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XIGDUO XR with food and drink and alcohol

Avoid excessive alcohol intake while taking XIGDUO XR since this may increase the risk of metabolic acidosis.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, 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. It is not known if this medicine passes into human breast milk.

Driving and using machines

XIGDUO XR has no or negligible influence on the ability to drive and use machines. Taking this medicine with other medicines or insulin used to treat your diabetes can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as weakness, dizziness, increased sweating, fast heartbeat, 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.

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XIGDUO XR contains lactose

XIGDUO XR contains lactose (milk sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to take XIGDUO XR:

Do not share medicines prescribed for you with any other person.

Always take XIGDUO XR exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure (refer 2.14).

The usual dose is:

XIGDUO XR 5 mg/ 500 mg - take one or two tablets once in the evening (dinner).

XIGDUO XR 5 mg/ 1000 mg – take one or two tablets once in the evening (dinner).

XIGDUO XR 10 mg/ 500 mg – take one tablet once in the evening (dinner).

XIGDUO XR 10 mg/ 1000 mg – take one tablet once in the evening (dinner).

The amount of XIGDUO XR 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.

Swallow the whole tablet with half a glass of water. Never crush, cut or chew the tablet.

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Take your tablet with food. This is to reduce the risk of side effects in the stomach.

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 insulin given by injection.

Remember to take these other medicine(s) as your doctor or pharmacist has told you. This will help get the best results for your health.

Your doctor and pharmacist will tell you how long your treatment with XIGDUO XR will last.

Do not stop treatment early. If you have the impression that the effect of XIGDUO XR is too strong or too weak, tell your doctor or pharmacist.

If you take more XIGDUO XR than you should:

If you take more XIGDUO XR tablets than you should, you may experience metabolic acidosis. Symptoms of metabolic 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 metabolic acidosis may lead to coma. Stop taking this medicine immediately and contact a doctor or the nearest hospital straight away. Take the medicine pack with you.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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If you forget to take XIGDUO XR:

Do not take a double dose of this medicine to make up for a forgotten dose.

If you stop taking XIGDUO XR:

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

XIGDUO XR can have side effects.

Not all side effects reported for XIGDUO XR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XIGDUO XR, please consult your healthcare provider for advice.

If any of the following happens, stop taking XIGDUO XR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching,
- fainting,

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- yellowing of the skin and eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to XIGDUO XR. You may need urgent medical attention or hospitalisation.

- very dry or sticky mouth, feeling very thirsty,
- feeling very sleepy or tired,
- passing little or no water (urine) and
- fast heart beat.

These are signs of losing too much fluid from your body (volume depletion or dehydration).

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

These are signs of metabolic acidosis. Metabolic acidosis may lead to coma and death.

- fever or chills,
- burning sensation when passing water (urinating),

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- pain in your back or side and
 - blood in your urine, although uncommon.

These are signs of a severe infection of the urinary tract.

- increased levels of “ketone bodies” in your urine or blood (shown on urine or blood tests),
- 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.

These are the signs of diabetic acidosis. This may occur regardless of blood glucose level.

Your doctor may decide to temporarily or permanently stop your treatment with XIGDUO XR.

These are all serious effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

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The following side effects have been frequently reported:

- low blood sugar levels (hypoglycaemia) - when taking this medicine with other medication or insulin to treat your diabetes. These are signs of low blood sugar (hypoglycaemia):
 - shaking, sweating, feeling very anxious, fast heartbeat,
 - feeling hungry, headache, change in vision and
 - a change in your mood or feeling confused.

Your doctor will tell you how to treat low blood sugar and what to do if you get any of the signs above.

- nausea
- vomiting
- diarrhoea or stomach-ache
- loss of appetite
- 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)
- changes in the amount of red blood cells in your blood (shown in tests)

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- changes in taste
 - dizziness
 - decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needle (parasthesia) 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.

The following side effects have been reported less frequently:

- thirst
- constipation
- discomfort when passing water (urine)
- awakening from sleep at night to pass urine
- dry mouth
- decreased weight
- changes in laboratory blood tests (creatinine or urea)
- decrease in kidney function
- abnormalities in liver function tests, inflammation of the liver (hepatitis)
- redness of the skin (erythema), itching or an itchy rash (hives)

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If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of XIGDUO XR.

5. How to store XIGDUO XR

XIGDUO XR 5 mg/ 500 mg: Store at or below 30 °C.

XIGDUO XR 5 mg/ 1000 mg: Store at or below 25 °C.

XIGDUO XR 10 mg/ 500 mg: Store at or below 30 °C.

XIGDUO XR 10 mg/ 1000 mg: Store at or below 30 °C.

Do not use XIGDUO XR after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Keep in the original packaging.

Do not remove the blister strips from the carton until required for use.

Store in a cool dry place away from direct sunlight.

Store all medicines out of reach of children.

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6. Contents of the pack and other information

What XIGDUO XR contains

The active substances are dapagliflozin and metformin hydrochloride.

Each XIGDUO XR 5mg/ 500mg film coated tablet contains 5 mg dapagliflozin and 500 mg metformin.

Each XIGDUO XR 5mg/ 1000mg film coated tablet contains 5 mg dapagliflozin and 1000 mg metformin.

Each XIGDUO XR 10mg/ 500mg film coated tablet contains 5 mg dapagliflozin and 500 mg metformin.

Each XIGDUO XR 10mg/ 1000mg film coated tablet contains 5 mg dapagliflozin and 1000 mg metformin.

The other ingredients are:

Tablet core: Carboxymethylcellulose sodium, crospovidone, hypromellose 2208, hypromellose 2910, lactose anhydrous (48 mg), magnesium stearate, microcrystalline cellulose and silicon dioxide.

Film-coating: FD & C yellow number 6/ Sunset Yellow FCF aluminium lake, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

What XIGDUO XR looks like and contents of the pack

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XIGDUO XR 5 mg/ 500 mg tablets are orange, capsule shaped, film-coated tablets

debossed with “1070” and “5/500” on one side and plain on the other side.

The dimension is approximately 19.8 mm x 10.2 mm x 7.2 mm

XIGDUO XR 5 mg/ 1000 mg tablets are pink to dark pink, biconvex, oval shaped, film-coated tablets debossed with “1071” and “5/1000” on one side and plain on the other side.

The dimension is approximately 20.3 mm x 10.8 mm x 8.0 mm

XIGDUO XR 10 mg/ 500 mg tablets are pink, biconvex, capsule shaped, film-coated tablets debossed with “1072” and “10/500” on one side and plain on the other side.

The dimension is approximately 19.8 mm x 10.2 mm x 7.2 mm

XIGDUO XR 10 mg/1 000 mg tablets are yellow to dark yellow, biconvex, oval shaped, film-coated tablets debossed with “1073” and “10/1000” on one side and plain on the other side.

The dimension is approximately 20.3 mm x 10.8 mm x 8.0 mm

XIGDUO XR tablets are available in aluminium/aluminium foil blister packs of 14, 28, 30, 56 and 60 tablets packed in a carton.

Not all pack sizes may be marketed.

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Holder of certificate of registration

AstraZeneca Pharmaceuticals (Pty) Limited

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XIGDUO XR 10 mg/ 500 mg (Tablets): 52/21.2/0412

XIGDUO XR 10 mg/ 1000 mg (Tablets): 52/21.2/0413

Access to the corresponding Professional Information

For the latest Professional Information, kindly scan the QR code on the carton.

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☎ (011) 797 6000