

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking XIGDUO XR?

XIGDUO XR contains two active ingredients, dapagliflozin and metformin hydrochloride. XIGDUO XR is used to lower blood sugar in people with type 2 diabetes mellitus. It can also reduce hospitalisation for heart failure in patients with type 2 diabetes.

For more information, see Section [1. Why am I taking XIGDUO XR?](#) in the full CMI.

2. What should I know before I take XIGDUO XR?

Do not use if you have ever had an allergic reaction to dapagliflozin or metformin hydrochloride, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take XIGDUO XR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with XIGDUO XR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take XIGDUO XR?

- Your Doctor will tell you how many XIGDUO XR tablets to take and how often you should take them.
- XIGDUO XR should be taken with or immediately after food in the evening. Swallow tablet whole with a full glass of water.

More instructions can be found in Section [4. How do I take XIGDUO XR?](#) in the full CMI.

5. What should I know while taking XIGDUO XR?

Things you should do	<ul style="list-style-type: none">• Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia (low blood sugar) and hyperglycaemia (high blood sugar) and know how to treat them.• Talk to your doctor if you are about to have surgery (including dental surgery), an X-ray or scan requiring an injection of iodinated contrast (dye) to discuss when to stop and start taking it again.• Remind any doctor, dentist or pharmacist you visit that you are taking XIGDUO XR.• If you become pregnant while taking XIGDUO XR, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how XIGDUO XR affects you
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your XIGDUO XR tablets in the blister until it is time to take them.• Keep your tablets in a cool dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while taking XIGDUO XR?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, some can be minor and temporary. However, some side effects may be serious and could require urgent medical attention or hospitalisation. See Section [6. Are there any side effects?](#) in the full CMI and, if you need to, ask your doctor if you have any further questions about side effects. Tell your doctor if you experience any side effects, including those not listed in this leaflet.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

XIGDUO XR®

Active ingredient(s): dapagliflozin/metformin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about taking XIGDUO XR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking XIGDUO XR.**

Where to find information in this leaflet:

- [1. Why am I taking XIGDUO XR?](#)
- [2. What should I know before I take XIGDUO XR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take XIGDUO XR?](#)
- [5. What should I know while taking XIGDUO XR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking XIGDUO XR?

XIGDUO XR contains two active ingredients dapagliflozin and metformin hydrochloride. Dapagliflozin is a member of a class of medicines you take by mouth called SGLT-2 (Sodium Glucose Cotransporter-2) inhibitors and metformin belongs to a class of medicines called biguanides.

XIGDUO XR is used with diet, exercise and sometimes other medicines such as insulin, a sulfonylurea, or a dipeptidyl peptidase (DPP-4) inhibitor, or a glucagon like peptide 1 (GLP-1) receptor agonist such as exenatide to control the levels of blood sugar (glucose) in patients with type 2 diabetes mellitus. It can also reduce hospitalisation for heart failure in patients with type 2 diabetes.

Type 2 diabetes mellitus

Type 2 diabetes mellitus (also called non-insulin-dependent diabetes mellitus, or NIDDM) is the condition of having high levels of blood sugar (hyperglycaemia). This is usually because your body does not make enough insulin and /or the insulin that your body produces does not work as well as it should. Left uncontrolled, the build-up of high levels of sugar in your blood can lead to serious medical problems.

The main goal of treating type 2 diabetes is to control your blood sugar to a normal level. Lowering and controlling blood sugar may help prevent or delay complications of diabetes, which include kidney disease, blindness and amputation.

2. What should I know before I take XIGDUO XR?

Warnings

Do not take XIGDUO XR if you:

- are allergic to dapagliflozin or metformin hydrochloride, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin or
 - you may feel faint
- Always check the ingredients to make sure you can take this medicine.
 - have type 1 diabetes mellitus that is well controlled by insulin alone
 - have type 2 diabetes that is already well controlled by diet alone
 - have any type of metabolic acidosis such as lactic acidosis or diabetic ketoacidosis. Symptoms of lactic acidosis may include feeling weak and tired, unusual muscle pain, trouble breathing, stomach pain with nausea and vomiting or diarrhoea, feeling cold specially in arms or legs, feeling dizzy or light-headed, having slow or irregular heart beat or your medical condition suddenly changes. Diabetic ketoacidosis is a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood. You may notice this as 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).
 - have had a diabetic pre-coma
 - have problems with your liver
 - drink excessive alcohol, binge drinking, alcohol dependence
 - have poorly functioning kidneys, severe kidney disease or kidney failure
 - have dehydration, severe blood loss, shock
 - have a severe infection
 - have certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)
 - have severe breathing difficulties
 - have blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
 - have gangrene
 - have inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting.

Talk to your doctor about when to stop taking XIGDUO XR and when to start taking it again if you:

- are going to have an X-ray or scan where you will be injected with an iodinated contrast (dye)
- are planning to have surgery (including where the use of insulin is essential).

XIGDUO XR contains dapagliflozin and metformin. If you have more than one medicine containing dapagliflozin or metformin in your possession, you may accidentally take too much (overdose). Accidentally taking too much metformin can cause a very serious side effect called lactic acidosis.

ACCIDENTAL METFORMIN OVERDOSING IS A SIGNIFICANT SAFETY RISK.

Ask your doctor or pharmacist if you are unsure if you have any other medicines containing metformin.

Metformin is sold under many different brand names in Australia. Your doctor or pharmacist will know which other medicines also contain metformin.

Check with your doctor if you:

- have any allergies to any other medicines, foods, dyes or preservatives.
- Have or have had any other medical conditions:
 - kidney, liver or pancreas problems
 - heart failure
 - frequently get genital or urinary tract infections (infections of the bladder, kidney, or tubes that carry urine)
 - an illness that will make you dehydrated such as diarrhoea or a severe infection.
- drink alcohol
- take any medicines for any other condition
- are lactose intolerant. XIGDUO XR tablets contain lactose.

Your doctor will do some tests for kidney function at the start of treatment and regularly while you are on treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take XIGDUO XR if you are pregnant or plan to become pregnant.

Tell your doctor if you are pregnant or intend to become pregnant.

The safety of XIGDUO XR in pregnant women has not been established. Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace XIGDUO XR with insulin while you are pregnant.

Do not take XIGDUO XR if you are breastfeeding.

Tell your doctor if you are breastfeeding or plan to breastfeed.

XIGDUO XR is not recommended while you are breastfeeding. Your doctor will discuss the options available to you.

Children

XIGDUO XR is not recommended for use in children.

It has not been studied in children younger than 18 years old.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Discard any other medicines containing dapagliflozin or metformin that your doctor might have prescribed to you in the past and that you may still have in your possession.

XIGDUO XR contains dapagliflozin and metformin. If you have more than one medicine containing dapagliflozin or metformin in your possession, you may accidentally take too much (overdose).

XIGDUO XR may affect how well other medicines work and some medicines can affect how well XIGDUO XR works.

These include:

- other medicines used to treat diabetes
- medicines that contain alcohol, such as cough and cold syrups
- tetracosactrin, a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits)
- danazol, a medicine used to treat endometriosis
- some medicines used to treat high blood pressure and some heart conditions, including beta-blockers, calcium channel blockers and ACE inhibitors
- medicines used to prevent blood clots, such as warfarin
- diuretics, also called fluid tablets
- chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve pain, swelling and other symptoms of inflammation, such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam
- cimetidine, a medicine used to treat reflux and ulcers
- corticosteroids such as prednisone or cortisone
- some medicines used to treat asthma such as salbutamol or terbutaline
- lithium, a medicine to treat and prevent mental illness, including mania or depression in a condition called bipolar disorder

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect XIGDUO XR.

4. How do I take XIGDUO XR?

How to take XIGDUO XR

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- **Swallow your XIGDUO XR tablet whole with a full glass of water.**
- **XIGDUO XR tablets must not be chewed or crushed.**

How much to take

- Your Doctor will tell you how many XIGDUO XR tablets to take and how often you should take them.
- The dose varies from person to person. Your doctor will decide the right dose for you.
- Your doctor may prescribe XIGDUO XR along with certain other medicines that lower blood sugar.

When to take XIGDUO XR

- **XIGDUO XR should be taken with or immediately after food in the evening.** This will reduce the chance of a stomach upset.
- **XIGDUO XR should be taken at approximately the same time each day.** Taking your tablets at the same

time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take

- **Continue taking your medicine for as long as your doctor tells you.** Make sure you keep enough XIGDUO XR to last over weekends and holidays.

XIGDUO XR helps control your condition, but does not cure it. Therefore, you must take XIGDUO XR every day.

If you forget to use XIGDUO XR

XIGDUO XR should be taken regularly at the same time each day. If you miss your dose at the usual time take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much XIGDUO XR

If you think that you have used too much XIGDUO XR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking XIGDUO XR?

Things you should do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking XIGDUO XR.

Talk to your doctor if you are having surgery (including dental surgery) or an X-ray or scan where you will be injected with a iodinated contrast (dye) to discuss when to stop taking XIGDUO XR and when to start taking it again.

If you become pregnant while taking XIGDUO XR, tell your doctor immediately.

If you need to have any medical tests while you are taking XIGDUO XR, tell your doctor.

XIGDUO XR may affect the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Like for all patients with diabetes it is important to check your feet regularly and adhere to any other advice regarding foot care given by your doctor.

Your doctor may want to perform blood tests to check your kidneys, liver, heart, vitamin B12 level and levels of cholesterol and fats in your blood while you are taking XIGDUO XR.

Metformin may reduce Vitamin B12 levels. Periodic monitoring may be necessary in patients at risk for Vitamin B12 deficiency.

Tell your doctor if you:

- become ill
- become dehydrated
- are injured
- have a fever
- have a serious infection
- are having surgery (including dental surgery).

Your blood glucose may become difficult to control at these times. You may also be more at risk of developing a serious condition called lactic acidosis or diabetic ketoacidosis. At these times, your doctor may temporarily replace XIGDUO XR with insulin.

Remind any doctor, dentist or pharmacist you visit that you are using XIGDUO XR.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia and hyperglycaemia and know how to treat them.

Hypoglycaemia

XIGDUO XR does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines, such as insulin or a sulfonylurea.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- light-headedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

- You can do this by doing one of the following:
- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

Hyperglycaemia

If you notice the return of any of the signs of hyperglycaemia, contact your doctor immediately.

Your doctor may need to consider additional or other treatments for your diabetes.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less XIGDUO XR than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Things you should not do

- Do not stop taking your medicine or change the dosage without checking with your doctor.
- Do not take XIGDUO XR to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how XIGDUO XR affects you.

Although rare, XIGDUO XR may cause dizziness in some people. Low blood sugar levels may also slow your reaction time and affect your ability to drive or operate machinery.

Make sure you know how you react to XIGDUO XR before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with XIGDUO XR may also lead to serious side effects. Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

Looking after your medicine

- **Keep your XIGDUO XR tablets in the blister until it is time to take them.** If you take XIGDUO XR out of the blister, it will not keep well.
- **Keep your tablets in a cool dry place where the temperature stays below 30°C.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut-related:</p> <ul style="list-style-type: none"> • nausea, vomiting or diarrhoea • stomach pain or discomfort <p>Nervous system-related:</p> <ul style="list-style-type: none"> • loss of appetite • loss of taste • headache <p>Others:</p> <ul style="list-style-type: none"> • back pain • rash 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> • Shortness of breath, wheezing or severe difficulty in breathing; shock, swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives on the skin, hayfever, or you may feel faint. <p>Hypoglycaemia:</p> <ul style="list-style-type: none"> • low blood sugar that persist despite administering sugar as described in Section 5. What should I know while taking XIGDUO XR? in this leaflet. Signs of low blood sugar may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, rapid heart beat, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers. Do not drive a car if you have signs of low blood sugar. <p>Serious kidney problems:</p> <ul style="list-style-type: none"> • If you have kidney problems, you should take XIGDUO XR only if your doctor tells you to. <p>Dehydration:</p> <ul style="list-style-type: none"> • Volume depletion (loss of needed fluids from the body). If you are unable to keep fluids down or if you have any of these symptoms 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>of too much loss of body fluids (volume depletion or dehydration) while taking XIGDUO XR: dry sticky mouth, severe thirst, severe diarrhoea or vomiting, dizziness, or urinating less often than normal or not at all.</p> <p>Infections related:</p> <ul style="list-style-type: none"> • Genital infections. If you experience painful urination, soreness and more severe irritation or redness and swelling of your genitals, or an unpleasant odour or discharge associated with your genitals. • Urinary tract infection. If you have symptoms, such as burning or pain when you pass urine, more frequent or urgent need to urinate, fever, chills, or blood in the urine, contact your doctor as soon as possible. • If you experience pain or tenderness, redness, swelling of the genitals or the area from the genitals to the rectum, fever, and generally feeling unwell. These may be symptoms of a rare but serious and potentially life-threatening infection called Necrotising fasciitis of the perineum (Fournier's gangrene) and you will require prompt treatment. <p>Diabetic ketoacidosis:</p> <ul style="list-style-type: none"> • In rare cases dapagliflozin one of the active ingredients in XIGDUO XR, may cause a serious condition called diabetic ketoacidosis. Symptoms of diabetic ketoacidosis may include feeling sick or being sick, difficulty breathing, severe thirst, feeling weak and tired, confusion, a sweet smell to your breath, a sweet or metallic taste in your mouth, a strange odour to your urine or sweat and frequent urination. 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. Diabetes ketoacidosis is a life-threatening condition. <p>Lactic Acidosis IN RARE CASES, METFORMIN, ONE OF THE MEDICINES IN XIGDUO XR, CAN CAUSE A SERIOUS</p>	

Serious side effects	What to do
<p>SIDE EFFECT CALLED LACTIC ACIDOSIS.</p> <p>LACTIC ACIDOSIS IS A MEDICAL EMERGENCY THAT CAN CAUSE DEATH AND MUST BE TREATED IN THE HOSPITAL. LACTIC ACIDOSIS IS CAUSED BY A BUILD-UP OF LACTIC ACID IN YOUR BLOOD.</p> <p>STOP TAKING XIGDUO XR IF YOU GET ANY OF THE FOLLOWING SYMPTOMS OF LACTIC ACIDOSIS AND SEE YOUR DOCTOR IMMEDIATELY or go straight to the Emergency Department at your nearest hospital:</p> <ul style="list-style-type: none"> • You feel very weak and tired. • You have unusual (not normal) muscle pain. • You have trouble breathing. • You have stomach pain with nausea and vomiting, or diarrhoea. • You feel cold, especially in your arms and legs. • You feel dizzy or light-headed. • You have a slow or irregular heart beat • Your medical condition suddenly changes. <p>The risk of lactic acidosis is higher in the elderly, those whose diabetes is poorly controlled, those with prolonged fasting, those with certain heart conditions, those who drink alcohol and those with kidney or liver problems.</p>	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Occasionally, XIGDUO XR may be associated with changes in your cholesterol or fats in your blood. These can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What XIGDUO XR contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• dapagliflozin 10 mg and metformin 500 mg• dapagliflozin 10 mg and metformin 1000 mg• dapagliflozin 5 mg and metformin 1000 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• microcrystalline cellulose• lactose• carmellose sodium• hypromellose• crospovidone• silicon dioxide• magnesium stearate• polyvinyl alcohol• titanium dioxide• macrogol 3350• purified talc• iron oxide yellow (10mg/1000mg tablets)• iron oxide red (10mg/500mg and 5mg/1000mg tablets)
Potential allergens	Lactose

Do not take this medicine if you are allergic to any of these ingredients.

XIGDUO XR tablets do not contain gluten or sucrose.

What XIGDUO XR looks like

- XIGDUO XR 10mg/500mg, pink, biconvex, capsule shaped, film-coated tablets with '1072' and '10/500' debossed on one side and plain on the other side. Available in blister packs of 7 and 28 tablets. (AUST R 211294).
- XIGDUO XR 10mg/1000mg, yellow to dark yellow, biconvex, oval shaped, film-coated tablets with '1073' and '10/1000' debossed on one side and plain on the other side. Available in blister packs of 7 and 28 tablets. (AUST R 211295).
- XIGDUO XR 5mg/1000mg, pink to dark pink, biconvex, oval shaped, film-coated tablets with '1071' and '5/1000' debossed on one side and plain on the other side. Available in blister packs of 14 and 56 tablets. (AUST R 211296).

Who distributes XIGDUO XR

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone:- 1800 805 342

This leaflet was prepared in July 2023.

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