

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 FORXIGA?

FORXIGA contains the active ingredient dapagliflozin. FORXIGA is used to lower blood sugar in people with type 2 diabetes mellitus. It can also reduce hospitalisation for heart failure in adults with type 2 diabetes. FORXIGA is also used with other medicines to treat heart failure and to slow the progression of kidney disease in adults.

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

2. What should I know before I take FORXIGA?

Do not take if you have ever had an allergic reaction to dapagliflozin 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 FORXIGA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FORXIGA 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 FORXIGA?

- The dose of FORXIGA is one 10 mg tablet once a day.
- Swallow your FORXIGA tablet whole with a full glass of water.

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

5. What should I know while taking FORXIGA?

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 having surgery (including dental surgery) to discuss when to stop taking FORXIGA and when to start taking it again.• Remind any doctor, dentist or pharmacist you visit that you are taking FORXIGA.• If you become pregnant while taking FORXIGA, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Although rare, FORXIGA 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.
Looking after your medicine	<ul style="list-style-type: none">• Keep your FORXIGA 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 degree Celsius.

For more information, see Section [5. What should I know while taking FORXIGA?](#) 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.

FORXIGA®

Active ingredient(s): dapagliflozin

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking FORXIGA?

FORXIGA contains the active ingredient dapagliflozin. FORXIGA is a member of a class of medicines you take by mouth called SGLT-2 (Sodium Glucose Cotransporter-2) inhibitors.

FORXIGA is used with diet, exercise and sometimes other medicines (which may include metformin; insulin; a sulfonylurea medicine such as gliclazide, glimepiride and glibenclamide; or a dipeptidyl peptidase-4 inhibitor [DPP 4 inhibitor] such as sitagliptin or saxagliptin or a glucagon like peptide 1 [GLP-1] receptor agonist such as exenatide) to control the levels of blood sugar (glucose) in adults with type 2 diabetes mellitus. It can also reduce hospitalisation for heart failure in adults with type 2 diabetes. FORXIGA is also used with other medicines to treat heart failure and to slow the progression of kidney disease in adults.

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.

- FORXIGA lowers the level of your blood sugar by removing the excess sugar from the body in the urine.
- FORXIGA by itself is unlikely to cause low blood sugar (hypoglycaemia) because it does not interfere with the insulin hormone that regulates blood sugar.

Heart failure

Heart failure occurs when the heart is weak and cannot pump enough blood to the lungs and the rest of the body. This can lead to serious medical problems and need for hospital care.

The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling.

FORXIGA helps protect your heart from getting weaker and improves your symptoms. It can lower the need to go to hospital.

Kidney disease

Some conditions such as diabetes and high blood pressure can lead to kidney problems. These problems develop slowly over several years. Good control of your blood sugar and blood pressure are important in keeping your kidneys healthy, but may not always prevent kidney damage from occurring.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why FORXIGA has been prescribed for you.

2. What should I know before I take FORXIGA?

Warnings

Do not take FORXIGA if:

- you are allergic to dapagliflozin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.

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

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:
 - type 1 diabetes mellitus
 - kidney, liver or pancreas problems
 - 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.
 - diabetic ketoacidosis. This 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.
- you are taking a medicine for high blood pressure or taking a water pill (diuretic).
- take any medicines for any other conditions.
- are lactose intolerant. FORXIGA tablets contain lactose.

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

Check with your doctor if you are pregnant or intend to become pregnant.

The safety of FORXIGA in pregnant women has not been established. FORXIGA must not be used during the second and third trimesters of your pregnancy. If you are pregnant, stop taking FORXIGA and speak with your doctor immediately as good control of your type 2 diabetes (control your blood sugar) is important while you are pregnant and it is not known if FORXIGA will harm your unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

FORXIGA should not be used while breastfeeding or if planning to breastfeed. It is not known if FORXIGA will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking FORXIGA.

Children

FORXIGA 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.

Tell your doctor or pharmacist if you are taking lithium because FORXIGA can lower the amount of lithium in your blood. FORXIGA can be taken with most other medicines.

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

4. How do I take FORXIGA?

How to take FORXIGA

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 FORXIGA tablet with a full glass of water.

How much to take

- The dose of FORXIGA is one 10 mg tablet once a day. You should not take more than one FORXIGA tablet per day.

Your doctor may prescribe FORXIGA along with certain other medicines.

When to take

- **FORXIGA should be taken once daily at any time of the day regardless of meals.** 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.

- FORXIGA tablets can be taken with or without food.

How long to take

- **Continue taking the tablets for as long as your doctor tells you. Make sure you keep enough FORXIGA to last over weekends and holidays.**

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

If you forget to take FORXIGA

FORXIGA 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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much FORXIGA

If you think that you have taken too much FORXIGA, 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 FORXIGA?

Things you should do

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

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

It is important to have regular check-ups with your doctor or diabetes centre.

If you have diabetes, it is important to check your feet regularly and adhere to any other advice regarding foot care given by your doctor.

Tell your doctor 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. These symptoms could be a sign of diabetic ketoacidosis.

Talk to your doctor if you are having surgery (including dental surgery) to discuss when to stop taking FORXIGA and when to start taking it again.

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

FORXIGA may affect the results of some tests.

Visit your doctor regularly for checkups.

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

Hypoglycaemia

FORXIGA 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
- lightheadedness, 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 FORXIGA than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

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.

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

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

Things you should not do

- Do not stop taking your medicine without checking with your doctor.
- Do not take FORXIGA to treat any other complaints unless your doctor tells you to.
- Do not give this 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 FORXIGA affects you.

Although rare, FORXIGA 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 FORXIGA before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or lightheaded.

Looking after your medicine

- **Keep your FORXIGA tablets in the blister until it is time to take them.** If you take FORXIGA out of the blister it will not keep well.
- **Keep it 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
<ul style="list-style-type: none"> irritation of the genitals caused by genital infection back pain headache 	<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 (hypoglycaemia) may become worse in people who already take another medication to treat diabetes, such as sulfonylureas or insulin. Tell your doctor if you take other diabetes medicines. If you have symptoms of low blood sugar, you should check your blood sugar and treat if low, then call your doctor. Signs of low blood sugar may include weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, rapid heartbeat, 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>Dehydration:</p> <ul style="list-style-type: none"> Volume depletion (loss of needed fluids from the body; dehydration). Tell your doctor if you are unable to keep fluids down or if you have any of these symptoms of too much loss of body fluids (volume depletion or dehydration) while taking FORXIGA: dry sticky mouth, severe thirst, severe diarrhoea or vomiting, dizziness, or urinating less often than normal or not at all. <p>Infections related:</p>	<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
<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. 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> <p>In rare cases dapagliflozin, the active ingredient in FORXIGA, 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>	

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.

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 FORXIGA contains

Active ingredient (main ingredient)	Dapagliflozin 10 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• microcrystalline cellulose• lactose• crospovidone• silicon dioxide• magnesium stearate• polyvinyl alcohol• titanium dioxide• macrogol 3350• purified talc• iron oxide yellow
Potential allergens	Lactose

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

FORXIGA tablets do not contain gluten or sucrose.

What FORXIGA looks like

FORXIGA tablets are available in one strength i.e. 10 mg. The tablets are film-coated, yellow, biconvex and diamond-shaped with "10" engraved on one side and "1428" engraved on the other side.

FORXIGA tablets are available in blister packs of 7 and 28. (AUST R 180147).

Who distributes FORXIGA

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone:- 1800 805 342

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