

# SEGLUROMET®

## Consumer Medicine Information (CMI) summary

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

▼ This medicine is new or being taken differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I taking SEGLUROMET?

SEGLUROMET contains the active ingredients ertugliflozin and metformin. SEGLUROMET can be used to lower your blood sugar alone or in combination with certain other medicines that lower blood sugar, along with a recommended diet and exercise program.

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

### 2. What should I know before I take SEGLUROMET?

Do not use if you have ever had an allergic reaction to ertugliflozin or metformin 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 SEGLUROMET?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with SEGLUROMET 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 SEGLUROMET?

- Take one tablet two times a day.

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

### 5. What should I know while taking SEGLUROMET?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking SEGLUROMET.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine suddenly unless your doctor tells you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how SEGLUROMET affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep SEGLUROMET in its original packaging in a cool dry place where the temperature stays below 30°C.</li></ul>

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

### 6. Are there any side effects?

Less serious side effects include yeast infections of the vagina or penis, changes in urination, low blood sugar if you take SEGLUROMET with insulin or certain other diabetes medicines

Serious side effects include dehydration (losing too much water from your body), ketoacidosis (increased ketones in your blood or urine), genital infection or urinary tract infection. In rare cases, metformin, one of the medicines in SEGLUROMET, can cause lactic acidosis. Stop taking SEGLUROMET and call your doctor right away if you get the following symptoms: feeling very weak and tired, dizzy or lightheaded, unusual muscle pain, trouble breathing, stomach pain with nausea and vomiting, or diarrhoea, cold in your hands or feet, a slow or irregular heartbeat.

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.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# SEGLUROMET

**Active ingredients:** *Ertugliflozin pyroglutamic acid/Metformin hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking SEGLUROMET. **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 SEGLUROMET.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking SEGLUROMET?

**SEGLUROMET contains the active ingredients ertugliflozin and metformin.** Ertugliflozin is a medicine called a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin is called a biguanide. Both medicines work together to lower blood sugar levels in patients with type 2 diabetes mellitus. SEGLUROMET helps remove sugar from the body through urination and by blocking sugar (glucose) production by the liver. SEGLUROMET by itself is unlikely to cause low blood sugar because it does not work when your blood sugar is low.

**SEGLUROMET can be used to lower your blood sugar (glucose) alone or in combination with certain other medicines, along with a recommended diet and exercise program.**

## 2. What should I know before I take SEGLUROMET?

### Warnings

**Do not take SEGLUROMET if:**

- you are allergic to ertugliflozin or metformin, 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.

- you have poorly functioning kidneys since ertugliflozin requires good functioning kidneys to work well
- have or have had increased ketones in the blood and urine (a condition called metabolic acidosis or diabetic ketoacidosis).
- have liver problems

- drink alcohol to excess, either every day or only from time to time or in the short term ("binge" drinking).
- have dehydration, severe blood loss, shock
- have a severe infection
- have gangrene
- have heart or blood vessel problems, including a recent heart attack or congestive heart failure
- have severe breathing difficulties
- have blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- have pancreatitis (symptoms include severe and persistent stomach pain, with or without vomiting)

**Tell your doctor if you:**

- have type 1 diabetes
- are going to have surgery
- are eating less due to illness, surgery, or a change in your diet
- have a condition that may cause dehydration (losing too much water from your body)
- have other kidney problems
- have or have had yeast infections of the vagina or penis
- take other diabetes medicines; you are more likely to get low blood sugar with certain medicines
- have allergies to any other medicines or other substances such as foods, preservatives or dyes.
- are going to get an injection of dye or contrast agents for an x-ray procedure. SEGLUROMET may need to be stopped for a short time. Talk to your doctor about when you should stop SEGLUROMET and when you should start SEGLUROMET again.

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?](#)

SEGLUROMET contains ertugliflozin and metformin. If you have more than one metformin-containing medicine 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.**

- Discard any other medicines containing ertugliflozin or metformin that your doctor might have prescribed to you in the past and that you may still have in your possession by taking it to any pharmacy for safe disposal.
- 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. He or she will know which other medicines also contain metformin.

## Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or intend to become pregnant. It is not known if SEGLUROMET may harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant. **Do not use SEGLUROMET if you are pregnant.**

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if SEGLUROMET passes into breast milk. Talk with your doctor about the best way to feed your baby if you take SEGLUROMET. **Do not use SEGLUROMET if you are breast-feeding or plan to breast-feed.**

## Children

It is not known if SEGLUROMET is safe and effective in children under 18 years of age.

## Elderly

In studies, ertugliflozin worked well in and was generally well-tolerated by older patients. People 65 years or older were more likely to get dehydrated while taking SEGLUROMET compared to younger patients. Elderly people are more likely to have kidney problems. No dose adjustment is necessary based on age.

## 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 herbal supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

SEGLUROMET may be taken with most medicines.

**Some medicines may interfere with SEGLUROMET and affect how it works.**

Be sure to tell your doctor if you are taking water pills (diuretics), as you may be more likely to get dehydrated. See Section 6. Are there any side effects?

When you take SEGLUROMET with certain other diabetes medicines, you are more likely to get low blood sugar. See Section 6. Are there any side effects?

Tell your doctor or pharmacist if you are taking lithium because SEGLUROMET can lower the amount of lithium in your blood.

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

## 4. How do I take SEGLUROMET?

### How much to take

- Take one tablet two times a day. Your doctor will decide the dose of SEGLUROMET suitable for you.
- Take SEGLUROMET until your doctor tells you to stop.

### When to take SEGLUROMET

- Take SEGLUROMET at about the same time each day.
- Take SEGLUROMET with food to lower your chance of an upset stomach.

## If you forget to take SEGLUROMET

SEGLUROMET should be taken regularly at the same times each day. If you miss your dose at the usual time, take it as soon as you remember.

**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 2 doses at the same time to make up for the dose you missed.**

## If you take too much SEGLUROMET

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

### Things you should do

- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SEGLUROMET.
- If you become pregnant while taking SEGLUROMET, tell your doctor immediately.
- Continue to take SEGLUROMET for as long as your doctor prescribes it so that you can continue to help control your blood sugar. This medicine helps to control your condition but will not cure it. It is important to keep taking your medicine even if you feel well.

### Call your doctor straight away if:

- your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery. The amount of diabetes medicine you need may change.
- you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier's Gangrene, which destroys the tissue under the skin. Fournier's Gangrene has to be treated immediately.

Remind any doctor, dentist or pharmacist you visit that you are taking SEGLUROMET.

### Things you should not do

- Do not stop taking this medicine suddenly or lower your dosage without checking with your doctor.
- Do not take SEGLUROMET to treat any other complaints unless your doctor tells you to.
- Do not give SEGLUROMET to anyone else, even if they have the same condition as you. Remember that your doctor has prescribed this medicine only for you.

## Foot care

Check your feet regularly and see your doctor if you notice any problems. Follow any other advice regarding foot care given by your doctor.

## Blood tests

Your doctor may do blood tests before you start SEGLUROMET and while you take it. These tests look to see if your blood sugar level is normal at that moment and how well you have managed your blood sugar over time (called haemoglobin A1c). Blood tests may show changes related to kidney function or reduced vitamin B12 level or high levels of bad cholesterol. Your doctor may change your dose of SEGLUROMET based on the results.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how SEGLUROMET affects you.**

SEGLUROMET has no or negligible influence on the ability to drive and use machines.

- Do not drive or use any tools or machines if you feel dizzy while taking SEGLUROMET.

Taking this medicine in combination with insulin or medicines called insulin secretagogues can cause blood sugar levels to drop too low, which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines.

## Drinking alcohol

Tell your doctor if you drink alcohol very often or drink a lot of alcohol in the short term ("binge" drinking).

## Looking after your medicine

- Keep SEGLUROMET in its original packaging in a cool dry place where the temperature stays below 30°C.

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 windowsills.

Do not take SEGLUROMET if the packaging is torn or shows signs of tampering.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

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

Do not take 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><b>Yeast infections of the vagina or penis</b></p> <ul style="list-style-type: none"><li>• in women, symptoms include bad smell from your vagina, white or yellow discharge coming out of your vagina that may be lumpy or look like cottage cheese and itchiness.</li><li>• in men, symptoms include swelling of the penis, red skin, itchiness or rash, bad smell and discharge coming out of your penis, pain in the skin around your penis. If you haven't been circumcised, it may be hard to pull back the skin around the tip of your penis.</li></ul> <p><b>Changes in urination</b></p> <ul style="list-style-type: none"><li>• urgent need to urinate more often, in larger amounts, or at night, or thirst</li></ul> <p><b>Low blood sugar (hypoglycaemia)</b></p> <p>If you take SEGLUROMET with insulin or certain other diabetes medicines, your blood sugar might get too low. Your doctor might need to lower the dose of your insulin or other diabetes medicine.</p> <ul style="list-style-type: none"><li>• headache</li><li>• drowsiness, dizziness or confusion, irritability or feeling jittery, sweating, weakness, fast heartbeat</li><li>• hunger</li></ul> <p><b>Other side effects</b></p> <ul style="list-style-type: none"><li>• Stomach discomfort, diarrhoea, nausea, vomiting</li><li>• Itching or blisters of the skin or redness or an itchy rash (urticaria)</li><li>• loss of appetite or changes in taste</li></ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Risk of Lactic acidosis</b></p> <p>SEGLUROMET may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. <b>Lactic acidosis is a medical emergency that can cause death and must be treated in hospital.</b></p> <p>The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical</p>	<p><b>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.</b></p>

Serious side effects	What to do
<p>conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).</p> <p>If any of the above apply to you, talk to your doctor for further instructions.</p> <p>Stop taking SEGLUROMET for a short time if you have a condition that may be associated with dehydration (significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.</p> <p><b>Stop taking SEGLUROMET and call your doctor right away if you get the following symptoms of lactic acidosis:</b></p> <ul style="list-style-type: none"> <li>• feeling very weak and tired, dizzy or lightheaded</li> <li>• unusual (not normal) muscle pain</li> <li>• trouble breathing</li> <li>• stomach pain with nausea and vomiting, or diarrhoea</li> <li>• feeling cold in your hands or feet</li> <li>• a slow or irregular heartbeat</li> </ul> <p>You have a higher chance of getting lactic acidosis if you:</p> <ul style="list-style-type: none"> <li>• have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye</li> <li>• drink a lot of alcohol (very often or short-term 'binge' drinking)</li> <li>• have surgery</li> <li>• have a heart attack, severe infection, or stroke</li> <li>• get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting or diarrhoea, exposure to heat, when you sweat a lot with activity or exercise, or if you drink less fluid than normal.</li> </ul> <p>Stop taking SEGLUROMET for a short time if you have a condition that may be associated with dehydration and talk to your doctor for further instructions.</p> <p><b>Dehydration (losing too much water from your body):</b></p> <ul style="list-style-type: none"> <li>• dry mouth, feeling dizzy, light-headed, or weak, especially when you stand up, fainting</li> </ul> <p>You may be more likely to get dehydrated if you:</p> <ul style="list-style-type: none"> <li>• have kidney problems or take water tablets (diuretics) or</li> <li>• are 65 years or older</li> </ul>	

Serious side effects	What to do
<p><b>Ketoacidosis (increased ketones in your blood or urine)</b></p> <ul style="list-style-type: none"> <li>• nausea or vomiting</li> <li>• tiredness or trouble breathing</li> <li>• stomach-area (abdominal) pain</li> <li>• excessive thirst</li> </ul> <p>If possible, check for ketones in your urine, even if your blood sugar is less than 14.0 mmol/L. You may need to be treated in a hospital.</p> <p><b>Genital infection</b></p> <p>A rare but serious bacterial infection that causes damage to the tissue under the skin (necrotising fasciitis) in the area between and around the anus and genitals (perineum). Necrotising fasciitis of the perineum has happened in women and men who take medicines that lower blood sugar in the same way as one of the medicines in SEGLUROMET. Necrotising fasciitis of the perineum may lead to hospitalisation, may require multiple surgeries, and may lead to death. Seek medical attention immediately if you have:</p> <ul style="list-style-type: none"> <li>• pain or tenderness, swelling, or redness of the skin (erythema) in the area between and around your anus and genitals</li> <li>• fever or you are feeling very weak, tired or uncomfortable (malaise)</li> </ul> <p><b>Urinary tract infection</b></p> <ul style="list-style-type: none"> <li>• burning or pain when you pass urine, more frequent or urgent need to urinate, fever, chills, or blood in the urine</li> </ul>	

**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](http://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 SEGLUROMET contains

<b>Active ingredient (main ingredient)</b>	ertugliflozin pyroglutamic acid, and metformin hydrochloride
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<b>Other ingredients (inactive ingredients)</b>	Povidone Microcrystalline cellulose Crospovidone Sodium lauryl sulfate Magnesium stearate Hypromellose Hyprolose Titanium dioxide Iron oxide red Carnauba wax
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SEGLUROMET does not contain gluten, sucrose, tartrazine or any other azo dyes.

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

#### **What SEGLUROMET looks like**

SEGLUROMET 2.5 /500 is a pink, oval, film-coated tablet debossed with '2.5/500' on one side and plain on the other side (AUST R 287636).

SEGLUROMET 2.5/1000 is a pink, oval, film-coated tablet debossed with '2.5/1000' on one side and plain on the other side (AUST R 287635).

SEGLUROMET 7.5 /500 is a red, oval, film-coated tablet debossed with '7.5/500' on one side and plain on the other side (AUST R 287633).

SEGLUROMET 7.5 /1000 is a red, oval, film-coated tablet debossed with '7.5/1000' on one side and plain on the other side (AUST R 287627).

#### **Who distributes SEGLUROMET**

Merck Sharp & Dohme (Australia) Pty Limited  
Level 1, Building A, 26 Talavera Road, Macquarie Park NSW 2113

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