▼**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.**

SEGLUROMET®

Ertugliflozin pyroglutamic acid/Metformin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SEGLUROMET.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SEGLUROMET against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What SEGLUROMET is used for

SEGLUROMET is used to help lower your blood sugar (glucose), which is too high because of your type 2 diabetes. SEGLUROMET can be used alone or in combination with certain other medicines that lower blood sugar, along with a recommended diet and exercise program.

Type 2 diabetes mellitus
Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM. Type 2 diabetes mellitus is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar builds up in the blood. This can lead to serious medical problems.

High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

Your doctor will do blood tests regularly to check your diabetes. These tests look to see if your blood sugar is normal at that moment (blood sugar levels) and how well you have managed your blood sugar over time (called haemoglobin A1c).

How SEGLUROMET works

SEGLUROMET contains two active ingredients - ertugliflozin and metformin hydrochloride. Ertugliflozin belongs to a group of medicines you take by mouth called SGLT2 (sodium-glucose co-transporter 2) inhibitors and metformin belongs to a class of medicines you take by mouth called biguanides. 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 (hypoglycaemia) because it does not work when your blood sugar is low.

Talk to your doctor about the symptoms of low blood sugar and high blood sugar.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you take SEGLUROMET

When you must not take it

Do not take SEGLUROMET if:

- **you have poorly functioning kidneys.**
- **you are allergic to any of the ingredients in SEGLUROMET 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.
- **you have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood and urine).**
- **you have problems with your liver.**
- **you drink alcohol to excess, either every day or only from time to time.**
- **you have dehydration, severe blood loss, shock**
- **you have a severe infection**
- **you have gangrene**
- **you have certain heart or blood vessel problems, including a recent heart attack or severe heart failure (when the heart fails to pump blood effectively)**
- **you have severe breathing difficulties**
- **you have blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)**
- **you have pancreatitis (symptoms include severe and persistent stomach pain, with or without vomiting)**
- **the packaging is torn or shows signs of tampering.**
- **the expiry date on the pack has passed.**
  If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking SEGLUROMET, talk to your doctor.

Before you start to take it

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.
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.

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.

Tell your doctor if you:

- have type 1 diabetes
- have or have had diabetic ketoacidosis (increased ketones in the blood or urine)
- are going to have surgery
- are eating less due to illness, surgery, or a change in your diet
- drink alcohol very often, or drink a lot of alcohol in the short term ("binge" drinking)
- have a condition that may cause dehydration (losing too much water from your body)
- have kidney problems
- take other diabetes medicines; you are more likely to get low blood sugar with certain medicines
- have liver problems
- 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.
- have heart problems, including congestive heart failure
- have or have had yeast infections of the vagina or penis

You may obtain further information from your doctor or pharmacist, who has more detailed information.

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 adult patients. Patients 65 years or older were more likely to get dehydrated while taking ertugliflozin compared to younger patients. Elderly people are more likely to have kidney problems. If you are elderly, your doctor may do tests to see if your kidneys are working correctly. No dose adjustment of ertugliflozin is necessary based on age.

Tell your doctor if you are pregnant or planning to become pregnant.
It is not known if SEGLUROMET may harm your unborn baby.

Do not use SEGLUROMET if you are pregnant.
If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.

Tell your doctor if you are breast-feeding or plan to breast-feed.
It is not known if SEGLUROMET passes into breast milk.

Do not use SEGLUROMET if you are breast-feeding or plan to breast-feed.

Talk with your doctor about the best way to feed your baby if you take SEGLUROMET.

Tell your doctor if you have allergies to any other medicines or other substances such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell him/her before you take any SEGLUROMET.

Taking other medicines

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

SEGLUROMET may be taken with most medicines.

Be sure to tell your doctor if you are taking water pills (diuretics), as you may be more likely to get dehydrated. See 'Side Effects'.

When you take SEGLUROMET with certain other diabetes medicines, you are more likely to get low blood sugar. See 'Side Effects'.

How to take SEGLUROMET

Follow all directions given to you by your doctor and pharmacist carefully.
They may differ from the information contained in this leaflet.

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

It is important to eat right and exercise while you take SEGLUROMET.

How much to take

The recommended dose is one tablet 2 times a day.

The strength of SEGLUROMET that you take will vary depending on your condition and the amount of ertugliflozin and metformin needed to control your blood sugar.

Your doctor may do blood tests before you start SEGLUROMET and while you take it. Your doctor may change your dose of SEGLUROMET based on the results.

When 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.

Tell your doctor right away if you have any of these conditions and follow your doctor's instructions.

When to take it

Take SEGLUROMET at about the same time each day.
Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take SEGLUROMET with food to lower your chance of an upset stomach.

How long to take it

Continue to take SEGLUROMET for as long as your doctor prescribes it so 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.

If you forget to take it

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule.

Do not take 2 doses of SEGLUROMET at the same time.

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131 126), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much SEGLUROMET. Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

While you are using SEGLUROMET

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SEGLUROMET.

Tell any other doctors and pharmacists who treat you that you are taking SEGLUROMET.

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

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

Tell your doctor immediately if you experience pain or tenderness, redness, swelling of the genitals or the area between the genitals and the anus, fever and feeling generally unwell.
These symptoms could be a sign of a rare but serious life-threatening infection called necrotising fasciitis of the perineum or Fournier's gangrene. Fournier's gangrene must be treated immediately.

Things you must not do

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.

Do not stop taking your medicines or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how SEGLUROMET affects you.
SEGLUROMET has no or negligible influence on the ability to drive and use machines. Taking this medicine in combination with insulin or medicines called insulin secretagogues can cause blood sugar levels to drop too low (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines.

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SEGLUROMET.

Like all prescription medicines, SEGLUROMET may cause side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice or have any of the following and they worry you:

- yeast infections of the vagina or penis Symptoms of yeast infection in women 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. Symptoms of yeast infection in men include swelling of the penis, if you haven't been circumcised, it may be hard to pull back the skin around the tip of your penis, red skin, itchiness or rash, bad smell and discharge coming out of your penis, pain in the skin around your penis.
- changes in urination, including urgent need to urinate more often, in larger amounts, or at night
- thirst
- vaginal itching
- diarrhoea
- nausea
- vomiting
- abdominal discomfort (stomach ache)
- loss of appetite
- changes in taste
- skin reactions such as redness, itching or an itchy rash (urticaria)

Tell your doctor if you experience any of the following other side effects, as some may be serious and require urgent medical attention:

RISK OF LACTIC ACIDOSIS

SEGLUROMET may cause a very rare, but very serious side effect called lactic acidosis, particularly ifyour kidneys are not working properly.

Lactic acidosis is a medical emergency that can cause death and must be treated in hospital.

The risk of developing lactic acidosis is also increased withuncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration, liver problems and any medical conditions in which a part of the body has areduced supply of oxygen (such as acute severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

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.

STOP TAKING SEGLUROMET AND CALL YOUR DOCTOR RIGHT AWAY IF YOU GET THE FOLLOWING SYMPTOMS OF LACTIC ACIDOSIS:

- 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 in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat

You have a higher chance of getting lactic acidosis if you:

- have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye
- drink a lot of alcohol (very often or short-term 'binge' drinking)
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhoea. Dehydration can also happen when you sweat a lot with activity or exercise and don't drink enough fluids.
- have surgery
- have a heart attack, severe infection, or stroke

Dehydration (losing too much water from your body)

Symptoms of dehydration are:

- dry mouth
- feeling dizzy, light-headed, or weak, especially when you stand up
- fainting

You may be more likely to get dehydrated if you

- have kidney problems
- take water tablets (diuretics)
- are 65 years or older

Ketoacidosis (increased ketones in your blood or urine)

Ketoacidosis has happened in people who have type 1 diabetes or type 2 diabetes, during treatment with products containing SGLT2 inhibitors. Ketoacidosis can be life-threatening and may need to be treated in a hospital.

Ketoacidosis can happen with SEGLUROMET even if your blood sugar is less than 14.0 mmol/L.

Stop taking SEGLUROMET and call your doctor right away if you think you have ketoacidosis. Symptoms of ketoacidosis may include:

- nausea
- tiredness
- vomiting
- trouble breathing
- stomach-area (abdominal pain)
- excessive thirst

If you get these symptoms during treatment with SEGLUROMET, if possible, check for ketones in your urine, even if your blood sugar is less than 14.0 mmol/L.

Low blood sugar (hypoglycaemia)

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 while you use SEGLUROMET.

Signs and symptoms of low blood sugar may include:

- headache
- drowsiness
- irritability
- hunger
- dizziness
- confusion
- sweating
- feeling jittery
- weakness
- fast heart beat

Kidney problems

Blood tests may show changes related to kidney function (for example, creatinine).

Urinary tract infection

If you take SEGLUROMET you may be at a greater risk for urinary tract infections. 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.

Higher levels of bad cholesterol, called LDL (a type of fat in your blood)

Some side effects (e.g. reduced vitamin B_{12} level) can only be found when your doctor does tests from time to time to check your progress.

These are not all possible side effects of SEGLUROMET. For more information, ask your doctor or pharmacist.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

After using SEGLUROMET

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep SEGLUROMET in its original packaging in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking SEGLUROMET or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SEGLUROMET comes as four strengths of tablets:

2.5 mg/500 mg tablet - pink, oval, film-coated tablet debossed with '2.5/500' on one side and plain on the other side.

2.5 mg/1000 mg tablet - pink, oval, film-coated tablet debossed with '2.5/1000' on one side and plain on the other side.

7.5 mg/500 mg tablet - red, oval, film-coated tablet debossed with '7.5/500' on one side and plain on the other side.

7.5 mg/1000 mg tablet - red, oval, film-coated tablets debossed with '7.5/1000' on one side and plain on the other side.

A box of SEGLUROMET contains 56 tablets. SEGLUROMET tablets may also be supplied in packs of 14 tablets to start treatment.

Not all packs may be supplied.

Ingredients

Active ingredients:

SEGLUROMET 2.5 /500: ertugliflozin pyroglutamic acid, equivalent to ertugliflozin 2.5 mg and metformin hydrochloride 500 mg per tablet

SEGLUROMET 2.5 /1000: ertugliflozin pyroglutamic acid, equivalent to ertugliflozin 2.5 mg and metformin hydrochloride 1000 mg per tablet

SEGLUROMET 7.5 /500: ertugliflozin pyroglutamic acid, equivalent to ertugliflozin 7.5 mg and metformin hydrochloride 500 mg per tablet

SEGLUROMET 7.5 /1000: ertugliflozin pyroglutamic acid, equivalent to ertugliflozin 7.5 mg and metformin hydrochloride 1000 mg per tablet

Inactive ingredients:

- Povidone
- Microcrystalline cellulose
- Crospovidone
- Sodium lauryl sulfate
- Magnesium stearate

Ingredients of film-coating:

- Hypromellose
- Hyprolose
- Titanium dioxide
- Iron oxide red
- Carnauba wax

SEGLUROMET does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

SEGLUROMET is supplied in Australia by:

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

Date of Preparation

This leaflet was prepared in May 2020

Australian Register Numbers:

SEGLUROMET 2.5 /500: 287636

SEGLUROMET 2.5 /1000: 287635

SEGLUROMET 7.5 /500: 287633

SEGLUROMET 7.5 /1000: 287627

This CMI leaflet was current at the time of printing. To check if it has been updated, please view our website www.msd-australia.com.au or ask your pharmacist.

(CCPPI-MK8835B-T-032018)