

- ▼ 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.

STEGLATRO®

Ertugliflozin pyroglutamic acid

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about STEGLATRO.

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 STEGLATRO 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 STEGLATRO is used for

STEGLATRO is used to lower your blood sugar (glucose), which is too high because of your type 2 diabetes.

STEGLATRO 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 STEGLATRO works

STEGLATRO is a member of a class of medicines you take by mouth called sodium-glucose co-transporter 2 (SGLT2)

inhibitors that lowers blood sugar levels in patients with type 2 diabetes mellitus.

STEGLATRO helps remove sugar from the body through urination.

STEGLATRO 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 STEGLATRO

When you must not take it

Do not take STEGLATRO if:

- **you have poorly functioning kidneys since STEGLATRO requires good functioning kidneys to work well**
- **you are allergic to any of the ingredients in STEGLATRO 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.

- **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 STEGLATRO, talk to your doctor.

Before you start to take it

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 kidney problems
- have liver problems, because STEGLATRO is not recommended for patients with severe liver disease
- take other diabetes medicines, you are more likely to get low blood sugar with certain medicines

- 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 STEGLATRO is safe and effective in children under 18 years of age.

Elderly:

In studies, STEGLATRO 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 STEGLATRO compared to younger patients. No dose adjustment is necessary based on age.

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

It is not known if STEGLATRO may harm your unborn baby.

Do not use 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 STEGLATRO passes into breast milk.

Do not use STEGLATRO 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 STEGLATRO.

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 STEGLATRO.

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.

STEGLATRO may be taken with most medicines.

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

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

How to take STEGLATRO

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 STEGLATRO.

How much to take

The recommended dose is one 5 mg or one 15 mg tablet once a day. Your doctor will decide the dose of STEGLATRO suitable for you.

Your doctor may do blood tests before you start STEGLATRO and while you take it. Your doctor may change your dose of STEGLATRO 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 STEGLATRO at the same time every morning.

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

STEGLATRO can be taken with or without food.

How long to take it

Continue to take STEGLATRO 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 STEGLATRO on the same day.

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 STEGLATRO. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using STEGLATRO

Things you must do

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

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

If you become pregnant while taking STEGLATRO, 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 STEGLATRO to treat any other complaints unless your doctor tells you to.

Do not give STEGLATRO 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 medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how STEGLATRO affects you.

STEGLATRO 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 STEGLATRO.

Side Effects

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

Like all prescription medicines, STEGLATRO 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

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

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 STEGLATRO even if your blood sugar is less than 14.0 mmol/L.

Stop taking STEGLATRO 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 STEGLATRO, 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 STEGLATRO 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 STEGLATRO.

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 STEGLATRO 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)

These are not all possible side effects of STEGLATRO. 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 STEGLATRO

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 STEGLATRO 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 STEGLATRO 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

STEGLATRO comes as two strengths of tablets:

- 5 mg tablet - A pink, triangular-shaped, film-coated tablet marked with '701' on one side and plain on the other side.
- 15 mg tablet - A red, triangular-shaped, film-coated tablet marked with '702' on one side and plain on the other side.

A box of STEGLATRO contains 28 tablets. STEGLATRO tablets may also be supplied in packs of 7 tablets to start treatment.

Not all packs may be supplied in Australia.

Ingredients

Active ingredient:

Ertugliflozin pyroglutamic acid, equivalent to ertugliflozin 5 or 15 mg per tablet

Inactive ingredients:

- Microcrystalline cellulose
- Lactose monohydrate
- Sodium starch glycollate Type A
- Magnesium stearate

Ingredients of film-coating:

- Hypromellose
- Lactose monohydrate
- Macrogol 3350
- Triacetin
- Titanium dioxide
- Iron oxide red

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

Supplier

STEGLATRO 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

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STEGLATRO 5 - AUST R: 287619

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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.

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