

- ▼ 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.

STEGLUJAN®

Ertugliflozin pyroglutamic acid/Sitagliptin phosphate monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about STEGLUJAN.

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 STEGLUJAN 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 STEGLUJAN is used for

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

STEGLUJAN contains two active ingredients - ertugliflozin and sitagliptin. Ertugliflozin belongs to a group of medicines you take by mouth called SGLT2 (sodium-glucose co-transporter 2) inhibitors and sitagliptin belongs to a class of medicines you take by mouth called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). Both medicines work together to lower blood sugar levels in patients with type 2 diabetes mellitus.

STEGLUJAN helps remove sugar from the body through urination, helps to improve the levels of insulin after a meal and decreases the amount of sugar made by the body.

STEGLUJAN 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 STEGLUJAN

When you must not take it

Do not take STEGLUJAN if:

- **you have poorly functioning kidneys since ertugliflozin requires good functioning kidneys to work well.**
- **you are allergic to any of the ingredients in STEGLUJAN 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 STEGLUJAN, 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 STEGLUJAN 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 STEGLUJAN is safe and effective in children under 18 years of age.

Elderly:

In studies, ertugliflozin and sitagliptin worked well in and were 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 is necessary based on age.

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

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

Do not use STEGLUJAN 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 STEGLUJAN passes into breast milk. Talk with your doctor about the best way to feed your baby if you take STEGLUJAN.

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

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 STEGLUJAN.

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.

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

How to take STEGLUJAN

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 STEGLUJAN.

How much to take

The recommended dose is one tablet once a day.

The strength of STEGLUJAN that you will take varies depending on your condition and the amount of ertugliflozin and sitagliptin needed to control your blood sugar.

Your doctor may do blood tests, including tests to monitor your kidney function, before you start STEGLUJAN and

while you take it. Your doctor may change your dose of STEGLUJAN 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 STEGLUJAN 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.

STEGLUJAN can be taken with or without food.

How long to take it

Continue to take STEGLUJAN 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 STEGLUJAN 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 STEGLUJAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using STEGLUJAN

Things you must do

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

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

If you become pregnant while taking STEGLUJAN, 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 STEGLUJAN to treat any other complaints unless your

doctor tells you to.

Do not give STEGLUJAN 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 STEGLUJAN affects you.

STEGLUJAN has no or negligible influence on the ability to drive and use machines. However, dizziness and drowsiness have been reported with sitagliptin, which may affect your ability to drive or use machines. Do not drive or use any tools or machines if you feel dizzy while taking STEGLUJAN.

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 or changes in vision and may affect your ability to drive and use machines.

Side Effects

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

Like all prescription medicines, STEGLUJAN 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
- signs of an infection of the breathing passages, including runny nose, sore throat, cough
- soreness in the back of the nose and throat and discomfort when swallowing
- headache
- flu-like symptoms

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

Stop taking STEGLUJAN 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 STEGLUJAN, if possible, check for ketones in your urine, even if your blood sugar is less than 2.5 mg/mL.

Low blood sugar (hypoglycaemia)

If you take STEGLUJAN 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 STEGLUJAN.

Signs and symptoms of low blood sugar may include:

- headache
- drowsiness
- irritability
- hunger
- dizziness
- confusion
- sweating
- feeling jittery

- weakness
- fast heart beat

Allergic reactions which may be serious including rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.

If you have an allergic reaction, stop taking STEGLUJAN and call your doctor right away. Your doctor may prescribe a medication to treat your allergic reaction and a different medication for your diabetes.

Pancreatitis - severe and persistent stomach pain, often with nausea and vomiting. Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking STEGLUJAN and call your doctor right away if you experience these symptoms.

Bullous pemphigoid -

Cases of a skin reaction called bullous pemphigoid that can require treatment in a hospital have been reported in patients receiving sitagliptin. Tell your doctor if you develop blisters or the breakdown of your skin (erosion). Your doctor may tell you to stop taking STEGLUJAN.

Kidney problems

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

Urinary tract infection

If you take STEGLUJAN 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)

Additional side effects have been reported in general use with sitagliptin, by itself and/or with other diabetes medicines:

- Kidney problems (sometimes requiring dialysis)
- Stomach discomfort
- Diarrhoea
- Vomiting
- Constipation
- Joint pain
- Muscle aches
- Arm or leg pain
- Back pain
- Itching
- Blisters

These are not all possible side effects of STEGLUJAN. 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 STEGLUJAN

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 STEGLUJAN 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 STEGLUJAN 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

STEGLUJAN comes as two strengths of tablets:

- 5 mg/100 mg tablet - A beige, almond-shaped, film-coated tablet marked with '554' on one side and plain on the other side.
- 15 mg/100 mg tablet - A brown, almond-shaped, film-coated tablet marked with '555' on one side and plain on the other side.

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

Not all packs may be supplied.

Ingredients

Active ingredients:

- STEGLUJAN 5 /100: ertugliflozin pyroglutamic acid, equivalent to ertugliflozin 5 mg and sitagliptin 100 mg per tablet

- STEGLUJAN 15 /100: ertugliflozin pyroglutamic acid, equivalent to ertugliflozin 15 mg and sitagliptin 100 mg per tablet

Inactive ingredients:

- Microcrystalline cellulose
- Calcium hydrogen phosphate
- Croscarmellose sodium
- Sodium stearyl fumarate
- Magnesium stearate

Ingredients of film-coating:

- Hypromellose
- Hyprollose
- Titanium dioxide
- Iron oxide red
- Iron oxide yellow
- Iron oxide black
- Carnauba wax

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

Supplier

STEGLUJAN 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 February 2019.

Australian Register Numbers:

- STEGLUJAN 5 /100: AUST R: 287630
- STEGLUJAN 15 /100: AUST R: 287626

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-MK8835A-T-032018)