EN

Seglurometᵀᴹ 2.5 mg/1,000 mg film-coated tablets Seglurometᵀᴹ 7.5 mg/1,000 mg film-coated tablets

ertugliflozin/metformin hydrochloride

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Seglurometis and what it is used for

What Seglurometis

Seglurometcontains two active substances, ertugliflozin and metformin.
- Ertugliflozin belongs to a group of medicines called sodium glucose co-transporter-2 (SGLT2) inhibitors.
- Metformin belongs to a group of medicines called biguanides.

What Seglurometis used for
- Seglurometlowers blood sugar levels in adult patients (aged 18 years and older) with type 2 diabetes.
- Seglurometcan be used instead of taking both ertugliflozin and metformin as separate tablets.
- Seglurometcan be used alone or with some other medicines that lower blood sugar.
- You need to keep following your food and exercise plan while taking Seglurometl.

How Seglurometworks
- Ertugliflozin works by blocking the SGLT2 protein in your kidneys. This causes blood sugar to be removed in your urine.
- Metformin works by inhibiting sugar (glucose) production in the liver.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin or 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 (glucose) builds up in the blood. This can lead to serious medical problems, like heart disease, kidney disease, blindness and poor circulation.

2. What you need to know before you take Seglurometl

Do not take Seglurometl
- if you are allergic to ertugliflozin or metformin or any of the other ingredients of this medicine (listed in section 6).
- if you have severely reduced kidney function or need dialysis.
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness, or your breath developing an unusual fruity smell.
- if you have a severe infection or are dehydrated.
- if you have recently had a heart attack or have severe circulatory problems, such as 'shock' or breathing difficulties.
- if you have liver problems.
- if you drink alcohol to excess (either regularly or from time to time).

Do not take Seglurometif any of the above apply to you. If you are not sure, talk to your doctor before taking Seglurometl.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before and while taking Seglurometl, if you:
- have kidney problems.
- have or have had yeast infections of the vagina or penis.
- have ever had serious heart disease or if you have had a stroke.
- have type 1 diabetes. Seglurometshould not be used to treat this condition.
- take other diabetes medicines; you are more likely to get low blood sugar with certain medicines.
- might be at risk of dehydration (for example, if you are taking medicines that increase urine production [diuretics] lower blood pressure or if you are over 65 years old). Ask about ways to prevent dehydration.
- 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, contact a doctor or the nearest hospital straight away. These symptoms could be a sign of "diabetic ketoacidosis" – a problem you can get with diabetes because of increased levels of "ketone bodies" in your urine or blood, seen in tests. 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.
- have had a lower limb amputation.

It is important to check your feet regularly and adhere to any other advice regarding foot care and adequate hydration given by your healthcare professional. You should notify your doctor immediately if you notice any wounds or discolouration, or if you experience any tenderness or pain in your feet. Some studies indicate that taking ertugliflozin may have contributed to an increase in cases of lower limb amputation (mainly of the toe).

Talk to your doctor immediately if 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.

When this medicine is used in combination with insulin or medicines that increase insulin release from the pancreas, low blood sugar (hypoglycaemia) can occur. Your doctor may reduce the dose of your insulin or other medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Risk of lactic acidosis

Seglurometmay cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced 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 Seglurometfor 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 Seglurometand contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma.
Symptoms of lactic acidosis include:
- vomiting
- stomach ache (abdominal pain)
- muscle cramps
- a general feeling of not being well with severe tiredness
- difficulty in breathing
- reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

If you need to have major surgery you must stop taking Seglurometduring and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Seglurometl.

During treatment with Seglurometl, your doctor will check your kidney function at least once a year or more frequently if you are elderly and/or if you have worsening kidney function.

Urine glucose

Because of how Seglurometworks, your urine will test positive for sugar (glucose) while you are on this medicine.

Children and adolescents

Children and adolescents below 18 years should not take this medicine. It is not known if this medicine is safe and effective when used in children and adolescents under 18 years of age.

Other medicines and Seglurometl

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You may need more frequent blood glucose and kidney function tests, or your doctor may need to adjust the dose of Seglurometl. In particular, tell your doctor:
- if you are taking medicines which increase urine production (diuretics).
- if you are taking other medicines that lower the sugar in your blood, such as insulin or medicines that increase insulin release from the pancreas.
- if you are taking medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib).
- if you are taking certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists).

If any of the above apply to you (or you are not sure), tell your doctor.

If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example, in the context of an X-ray or scan, you must stop taking Seglurometbefore or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Seglurometl.

Seglurometwith alcohol

Avoid excessive alcohol intake while taking Seglurometsince this may increase the risk of lactic acidosis (see section "Warnings and precautions").

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known if Seglurometcan 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. You should not use Seglurometif you are pregnant.

It is not known if Seglurometpasses into breast milk. Talk with your doctor about the best way to feed your baby if you take this medicine.
You should not use Seglurometif you are breast-feeding.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines. Taking this medicine in combination with insulin or medicines that increase insulin release from the pancreas 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 Seglurometl.

Seglurometcontains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Seglurometl

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take
- The recommended dose of Seglurometis one tablet twice a day.
- The dose of Seglurometthat you take will depend on your condition and the amount of ertugliflozin and metformin needed to control your blood sugar.
- Your doctor will prescribe the right dose for you. Do not change your dose unless your doctor has told you to.

Taking this medicine
- Swallow the tablet; if you have difficulties in swallowing the tablet can be broken or crushed.
- Take one tablet twice daily. Try to take it at the same time each day; this will help you remember to take it.
- It is best to take your tablet with a meal. This will lower your chance of having an upset stomach.
- You need to keep following your food and exercise plan while taking Seglurometl.

If you take more Seglurometthan you should

If you take too much Seglurometl, talk to a doctor or pharmacist straight away.

If you forget to take Seglurometl

If you forget a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and go back to your regular schedule.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Seglurometl

Do not stop taking this medicine without talking to your doctor. Your blood sugar levels may increase if you stop the medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact a doctor or the nearest hospital straight away if you have any of the following serious side effects:

Lactic acidosis (very rare, may affect up to 1 in 10,000 people)

Seglurometmay cause a very rare, but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens, you must stop taking Seglurometand contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

Diabetic ketoacidosis (rare, may affect up to 1 in 1,000 people)

These are the signs of diabetic ketoacidosis (see also section "Warnings and precautions"):
- increased levels of "ketone bodies" in your urine or blood
- 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

This may occur regardless of blood glucose level. Your doctor may decide to temporarily or permanently stop your treatment with Seglurometl.

Necrotising fasciitis of the perineum or Fournier's gangrene (not known, cannot be estimated from the available data)

A serious soft tissue infection of the genitals or the area between the genitals and the anus (see section "Warnings and precautions" for symptoms).

If you notice any of the side effects above, contact a doctor or the nearest hospital straight away.

Contact your doctor as soon as possible if you notice the following side effects:

Dehydration (losing too much water from your body; common, may affect up to 1 in 10 people)

Symptoms of dehydration include:
- 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 medicines that increase your urine production (diuretics) or lower blood pressure
- are 65 years or older

Low blood sugar (hypoglycaemia; common)

Your doctor will tell you how to treat low blood sugar and what to do if you have any of the symptoms or signs below. The doctor may lower the dose of your insulin or other diabetes medicine.
Signs and symptoms of low blood sugar may include:
- headache
- drowsiness
- irritability
- hunger
- dizziness
- confusion
- sweating
- feeling jittery
- weakness
- fast heart beat

If you notice any of the side effects above, contact your doctor as soon as possible.

Other side effects include:

Very common
- vaginal yeast infection (thrush)
- feeling sick (nausea)
- vomiting
- diarrhoea
- stomach ache
- loss of appetite

Common
- yeast infections of the penis
- changes in urination, including urgent need to urinate more often, in larger amounts, or at night
- thirst
- vaginal itching
- change in taste
- blood tests may show changes in the amount of urea in your blood
- blood tests may show changes in the amount of total and bad cholesterol (called LDL - a type of fat in your blood)
- blood tests may show changes in the amount of red blood cells in your blood (called haemoglobin)

Uncommon (may affect up to 1 in 100 people)
- blood tests may show changes related to kidney function (such as 'creatinine')
- painful urination

Very rare
- decreased vitamin B_{12} levels. This may cause anaemia (low levels of red blood cells).
- liver function test disorders
- hepatitis (a liver problem)
- hives
- redness of the skin
- itching

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Seglurometl

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Don't store above 30° C, store in the original package.

Do not use this medicine if the packaging is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Seglurometcontains
- The active substances are ertugliflozin and metformin.
  - Each Seglurometl 2.5 mg/1,000 mg film-coated tablet contains 2.5 mg ertugliflozin (as ertugliflozin L-pyroglutamic acid) and 1,000 mg of metformin hydrochloride.
  - Each Seglurometl 7.5 mg/1,000 mg film-coated tablet contains 7.5 mg ertugliflozin (as ertugliflozin L-pyroglutamic acid) and 1,000 mg of metformin hydrochloride.
- The other ingredients are:
  - Tablet core: povidone (K29-32), microcrystalline cellulose , crospovidone , sodium lauryl sulfate , magnesium stearate .
- Film coating:
  - Seglurometl 2.5 mg/1,000 mg tablets and Seglurometl 7.5 mg/1,000 mg tablets: hypromellose , hydroxypropyl cellulose , titanium dioxide , iron oxide red , carnauba wax.

What Seglurometlooks like and contents of the pack
- Seglurometl 2.5 mg/1,000 mg film-coated tablets (tablets) are pink, film-coated tablets debossed with "2.5/1000" on one side and plain on the other side.
- Seglurometl 7.5 mg/1,000 mg film-coated tablets (tablets) are red, film-coated tablets debossed with "7.5/1000" on one side and plain on the other side.

Seglurometis available in Alu/PVC/PA/Alu blisters. The pack sizes are 14, 28 (4x7), 56, 60 (10x6) , 168, and 180 film-coated tablets in non-perforated blisters, multipack containing 196 (4 packs of 49) film coated tablets in non-perforated blisters and 30x1 film-coated tablets in perforated unit dose blisters.

Not all strengths and pack sizes may be marketed.

Manufacturer:
MSD International GmbH (P.R) LLC,
PRIDCO Industrial park, state Road 183,
Las Piedras, P.R, 00771
USA

Release site & Marketing Authorisation Holder :
Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

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(THIS IS A MEDICAMENT)
-Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
-Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament.
-The doctor and the pharmacist are experts in medicine, its benefits and risks.
-Do not by yourself interrupt the period of treatment prescribed for you.
-Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists