

PACKAGE LEAFLET

Package leaflet: Information for the patient

Linagliptin/Metformin hydrochloride Rowex 2.5 mg/850 mg film-coated tablets Linagliptin/Metformin hydrochloride Rowex 2.5 mg/1000 mg film-coated tablets

linagliptin/metformin hydrochloride

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 Linagliptin/Metformin hydrochloride Rowex is and what it is used for
2. What you need to know before you take Linagliptin/Metformin hydrochloride Rowex
3. How to take Linagliptin/Metformin hydrochloride Rowex
4. Possible side effects
5. How to store Linagliptin/Metformin hydrochloride Rowex
6. Contents of the pack and other information

1. What Linagliptin/Metformin hydrochloride Rowex is and what it is used for

The name of your tablet is Linagliptin/Metformin hydrochloride Rowex. It contains two different active substances linagliptin and metformin.

- Linagliptin belongs to a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors).
- Metformin belongs to a class of medicines called biguanides.

How Linagliptin/Metformin hydrochloride Rowex works

The two active substances work together to control blood sugar levels in adult patients with a form of diabetes called 'type 2 diabetes mellitus'. Along with diet and exercise, this medicine helps to improve the levels and effects of insulin after a meal and lowers the amount of sugar made by your body.

This medicine can be used alone or with certain other medicines for diabetes like sulphonylureas or insulin.

What is type 2 diabetes?

Type 2 diabetes 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 (glucose) builds up in the blood. This can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation.

2. What you need to know before you take Linagliptin/Metformin hydrochloride Rowex

Do not take Linagliptin/Metformin hydrochloride Rowex:

- if you are allergic to linagliptin or metformin or any of the other ingredients of this medicine (listed in section 6)

- if you have severely reduced kidney function
- 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 ever had a diabetic pre-coma
- if you have a severe infection such as an infection affecting your lung or bronchial system or your kidney. Severe infections may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- if you have lost a lot of water from your body (dehydration), e.g. due to long-lasting or severe diarrhoea, or if you have vomited several times in a row. Dehydration may lead to kidney problems, which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- if you are treated for acute heart failure or have recently had a heart attack, have severe problems with your circulation (such as shock) or have breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis (see 'Warnings and precautions').
- if you have liver problems
- if you drink alcohol to excess, either every day or only from time to time (see section 'Linagliptin/Metformin hydrochloride Rowex with alcohol').

Do not take Linagliptin/Metformin hydrochloride Rowex if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Linagliptin/Metformin hydrochloride Rowex

- if you have type 1 diabetes (your body does not produce any insulin). Linagliptin/Metformin hydrochloride Rowex should not be used to treat this condition.
- if you are using insulin or taking an anti-diabetic medicine known as ‘sulphonylurea’, your doctor may want to reduce your dose of insulin or sulphonylurea when you take either of them together with Linagliptin/Metformin hydrochloride Rowex in order to avoid low blood sugar (hypoglycaemia).
- if you have or have had a disease of the pancreas.

If you have symptoms of acute pancreatitis, like persistent, severe abdominal pain, you should consult your doctor.

If you encounter blistering of the skin it may be a sign for a condition called bullous pemphigoid. Your doctor may ask you to stop Linagliptin/Metformin hydrochloride Rowex.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before taking this medicine.

Diabetic skin problems are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse.

Risk of lactic acidosis.

Due to the metformin component, Linagliptin/Metformin hydrochloride Rowex may cause a very rare, but very serious complication 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.

Talk to your doctor promptly for further instructions if:

- You are known to suffer from a genetically inherited disease affecting mitochondria (the energy-producing components within cells) such as MELAS syndrome (Mitochondrial Encephalopathy, myopathy, Lactic acidosis and Stroke-like episodes) or Maternal inherited diabetes and deafness (MIDD).
- You have any of these symptoms after starting metformin: seizure, declined cognitive abilities, difficulty with body movements, symptoms indicating nerve damage (e.g. pain or numbness), migraine and deafness.

Stop taking Linagliptin/Metformin hydrochloride Rowex 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 instruction.

Stop taking Linagliptin/Metformin hydrochloride Rowex and 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,
- stomachache (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 Linagliptin/Metformin hydrochloride Rowex during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Linagliptin/Metformin hydrochloride Rowex.

During treatment with Linagliptin/Metformin hydrochloride Rowex, 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.

Children and adolescents

This medicine is not recommended for use in children and adolescents under 18 years. It is not effective in children and adolescents between the ages of 10 and 17 years. It is not known if this medicine is safe and effective when used in children younger than 10 years.

Other medicines and Linagliptin/Metformin hydrochloride Rowex

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 Linagliptin/Metformin hydrochloride Rowex before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Linagliptin/Metformin hydrochloride Rowex.

Tell your doctor 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 dosage of Linagliptin/Metformin hydrochloride Rowex. It is especially important to mention the following:

- medicines which increase urine production (diuretics)

- medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such as ibuprofen and celecoxib)
- certain medicines for the treatment of high blood pressure (ACE inhibitors and angiotensin II receptor antagonists)
- medicines that may change the amount of metformin in your blood, especially if you have reduced kidney function (such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib)
- carbamazepine, phenobarbital or phenytoin. These may be used to control fits (seizures) or chronic pain.
- rifampicin. This is an antibiotic used to treat infections such as tuberculosis.
- medicines used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- bronchodilators (β -sympathomimetics) for the treatment of bronchial asthma
- alcohol-containing medicines.

Linagliptin/Metformin hydrochloride Rowex with alcohol

Avoid excessive alcohol intake while taking Linagliptin/Metformin hydrochloride Rowex since 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.

You should not use Linagliptin/Metformin hydrochloride Rowex if you are pregnant. It is unknown if this medicine is harmful to the unborn child.

Metformin passes into human milk in small amounts. It is not known whether linagliptin passes into human milk. Talk to your doctor if you want to breast-feed while taking this medicine.

Driving and using machines

Linagliptin/Metformin hydrochloride Rowex has no or negligible influence on the ability to drive and use machines.

However, taking Linagliptin/Metformin hydrochloride Rowex in combination with medicines called sulphonylureas or with insulin can cause too low blood sugar level (hypoglycaemia), which may affect your ability to drive and use machines or work without safe foothold.

Linagliptin/Metformin hydrochloride Rowex contains sodium

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

3. How to take Linagliptin/Metformin hydrochloride Rowex

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 amount of Linagliptin/Metformin hydrochloride Rowex that you will take varies depending on your condition and the doses you currently take of metformin and/or individual tablets of linagliptin and metformin. Your doctor will tell you exactly the dose of this medicine to take.

How to take this medicine

- one tablet twice daily by mouth in the dose prescribed by your doctor.

- with meals to lower your chance of an upset stomach.

You should not exceed the maximum recommended daily dose of 5 mg linagliptin and 2,000 mg metformin hydrochloride.

Continue to take Linagliptin/Metformin hydrochloride Rowex as long as your doctor prescribes it so you can continue to help control your blood sugar. Your doctor may prescribe this medicine together with another oral anti-diabetic medicine or insulin. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

You should continue your diet during treatment with Linagliptin/Metformin hydrochloride Rowex and take care that your carbohydrate intake is equally distributed over the day. If you are overweight, continue your energy-restricted diet as instructed. This medicine alone is unlikely to cause abnormally low blood sugar (hypoglycaemia). When Linagliptin/Metformin hydrochloride Rowex is used with a sulphonylurea medicine or with insulin, low blood sugar can occur and your doctor may reduce the dose of your sulphonylurea or insulin.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Linagliptin/Metformin hydrochloride Rowex than you should

If you take more Linagliptin/Metformin hydrochloride Rowex tablets than you should have, you may experience lactic acidosis. Symptoms of lactic acidosis are non-specific such as feeling or being very sick, vomiting, stomachache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heartbeat.

If this happens to you, you may need immediate hospital treatment, as lactic acidosis can lead to coma. Stop taking this medicine immediately and contact a doctor or the nearest hospital straight away (see section 2). Take the medicine pack with you.

If you forget to take Linagliptin/Metformin hydrochloride Rowex

If you forget to take a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. Never take two doses at the same time (morning or evening).

If you stop taking Linagliptin/Metformin hydrochloride Rowex

Keep taking Linagliptin/Metformin hydrochloride Rowex until your doctor tells you to stop. This is to help keep your blood sugar under control.

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.

Some symptoms need immediate medical attention

You should stop taking Linagliptin/Metformin hydrochloride Rowex and see your doctor straight away if you experience the following symptoms of low blood sugar (hypoglycaemia): trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change, or confusion. Hypoglycaemia (frequency very common (may affect more than 1 in 10 people)) is an identified side effect for the combination of Linagliptin/Metformin hydrochloride Rowex plus sulphonylurea and for the combination Linagliptin/Metformin hydrochloride Rowex plus insulin.

Linagliptin/Metformin hydrochloride Rowex may cause a very rare (may affect up to 1 user in 10,000), but very serious side effect called lactic acidosis (see section 'Warnings and precautions'). If this

happens you **must stop taking Linagliptin/Metformin hydrochloride Rowex and contact a doctor or the nearest hospital immediately**, as lactic acidosis may lead to coma.

Some patients have experienced inflammation of the pancreas (pancreatitis; frequency rare, may affect up to 1 in 1,000 people).

STOP taking Linagliptin/Metformin hydrochloride Rowex and contact a doctor immediately if you notice any of the following serious side effects:

- Severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis).

Other side effects of Linagliptin/Metformin hydrochloride Rowex include:

Some patients have experienced allergic reactions (frequency rare), which may be serious, including wheezing and shortness of breath (bronchial hyperreactivity; frequency uncommon (may affect up to 1 in 100 people)). Some patients experienced rash (frequency uncommon), hives (urticaria; frequency rare), and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing (angioedema; frequency rare). If you experience any of the signs of illness mentioned above, stop taking Linagliptin/Metformin hydrochloride Rowex and call your doctor right away. Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Some patients have had the following side effects while taking Linagliptin/Metformin hydrochloride Rowex:

- Common (may affect up to 1 in 10 people): diarrhoea, blood enzyme increase (lipase increase), feeling sick (nausea)
- Uncommon: inflamed nose or throat (nasopharyngitis), cough, loss of appetite (decreased appetite), being sick (vomiting), blood enzyme increase (amylase increase), itching (pruritus)
- Rare: blistering of skin (bullous pemphigoid).

Some patients have experienced the following side effects while taking Linagliptin/Metformin hydrochloride Rowex with insulin

- Uncommon: liver function disorders, constipation.

Side effects when taking metformin alone, that were not described for Linagliptin/Metformin hydrochloride Rowex:

- Very common: abdominal pain.
- Common (may affect up to 1 in 10 people): a metallic taste (taste disturbance), decreased or low vitamin B12 levels in the blood (symptoms may include extreme tiredness (fatigue), a sore and red tongue (glossitis), pins and needles (paraesthesia) or pale or yellow skin). Your doctor may arrange some tests to find out the cause of your symptoms because some of these may also be caused by diabetes or due to other unrelated health problems.
- Very rare (may affect up to 1 in 10,000 people): hepatitis (a problem with your liver), skin reaction as redness of the skin (erythema).

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. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Linagliptin/Metformin hydrochloride Rowex

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 carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Linagliptin/Metformin hydrochloride Rowex contains

- The active substances are linagliptin and metformin hydrochloride.
Each Linagliptin/Metformin hydrochloride Rowex 2.5 mg/850 mg film-coated tablet contains 2.5 mg of linagliptin and 850 mg of metformin hydrochloride.
- Each Linagliptin/Metformin hydrochloride Rowex 2.5 mg/1,000 mg film-coated tablet contains 2.5 mg of linagliptin and 1,000 mg of metformin hydrochloride.
- The other ingredients are:
- Tablet core: copovidone, maize starch, sodium carbonate anhydrous (E500), crospovidone type A (E1202), magnesium stearate (E470b), silica, colloidal anhydrous (E551)
- Film coating: hypromellose 2910, 5mPas (E464), titanium dioxide (E171), talc (E553b), propylene glycol (E1520), red iron oxide (E172). Linagliptin/Metformin hydrochloride Rowex 2.5 mg/850 mg film-coated tablets also contain yellow iron oxide (E172).

What Linagliptin/Metformin hydrochloride Rowex looks like and contents of the pack

Linagliptin/Metformin hydrochloride Rowex 2.5 mg/850 mg are beige, oval-shaped, biconvex film-coated tablets (tablets) with a break-line on one side and debossed with '2.5/850' on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Linagliptin/Metformin hydrochloride Rowex 2.5 mg/1,000 mg are pink, oval-shaped, biconvex film-coated tablets (tablets) with a break-line on one side and debossed with '2.5/1000' on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Linagliptin/Metformin hydrochloride Rowex is available in blisters in packs containing 10, 30, 56, 60 and 90 film-coated tablets and multipacks containing 180 (2 packs of 90) and 180 (3 packs of 60) film-coated tablets.

Linagliptin/Metformin hydrochloride Rowex is available in perforated unit dose blisters in packs containing 10 x 1, 30 x 1, 56 x 1, 60 x 1 and 90 x 1 film-coated tablets and multipacks containing 180 x 1 (2 packs of 90 x 1) and 180 x 1 (3 packs of 60 x 1) film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

PharOS MT Ltd. HF62X, Hal Far Industrial Estate, Birzebbugia BBG3000, Malta.

Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

PharOS Pharmaceutical Oriented Services Ltd., Lesvou Street End, Thesi Loggos Industrial Zone, Metamorfossi, 144 52, Greece.

This medicine is authorised in the Member States of the European Economic Area

under the following names:

- AT Linagliptin/Metformin Sandoz 2,5 mg/850 mg – Filmtabletten
Linagliptin/Metformin Sandoz 2,5 mg/1000 mg – Filmtabletten
- CZ Linagliptin/Metformin
- ES Linagliptina/Metformina Sandoz 2,5 mg/850 mg comprimidos recubiertos con película EFG
Linagliptina/Metformina Sandoz 2,5 mg/1.000 mg comprimidos recubiertos con película EFG
- FI Linagliptin/Metformin Sandoz 2,5 mg/850 mg tabletti, kalvopäällysteinen
Linagliptin/Metformin Sandoz 2,5 mg/1000 mg tabletti, kalvopäällysteinen
- HU Linagliptin/Metformin Sandoz 2,5 mg/850 mg filmtabletta
Linagliptin/Metformin Sandoz 2,5 mg/1000 mg filmtabletta
- IE Linagliptin/Metformin hydrochloride Rowex 2.5 mg/850 mg film-coated tablets
Linagliptin/Metformin hydrochloride Rowex 2.5 mg/1000 mg film-coated tablets
- PT Metformina + Linagliptina Sandoz
- SK Linagliptin/Metformin Sandoz 2,5 mg/850 mg
Linagliptin/Metformin Sandoz 2,5 mg/1000 mg

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