

Jentadueto® 2.5 mg / 850 mg film-coated tablets

Jentadueto® 2.5 mg / 1,000 mg film-coated tablets

linagliptin/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:

- What Jentadueto is and what it is used for
- What you need to know before you take Jentadueto
- How to take Jentadueto
- Possible side effects
- How to store Jentadueto
- Contents of the pack and other information

1. What Jentadueto is and what it is used for

The name of your tablet is Jentadueto. 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 Jentadueto 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’. This medicine helps to improve the levels of insulin after a meal and lowers the amount of sugar made by your body.

Along with diet and exercise, this medicine helps lower your blood sugar. Jentadueto can be used alone or with certain other medicines for diabetes like sulphonylureas or insulin.

What is type 2 diabetes?

Type 2 diabetes is also called non-insulin-dependent diabetes mellitus, or NIDDM. 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Jentadueto

- if you have type 1 diabetes (your body does not produce any insulin). Jentadueto should not be used to treat these conditions.
- if you are taking insulin or 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 Jentadueto in order to avoid low blood sugar (hypoglycaemia).
- during treatment with Jentadueto, your doctor will check your kidney function at least once a year and more frequently if you are elderly or if your kidney function is borderline or at risk of worsening.
- if you are going to have an operation under general, spinal or epidural anaesthetic. You may need to stop taking Jentadueto for a couple of days before and after the procedure.
- if you are going to have an X-ray where you will be injected with a dye. You will need to stop taking Jentadueto prior to, or at the time of the X-ray and for 2 or more days after. Before taking Jentadueto again, your kidney function should be tested.
- 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 are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before taking Jentadueto.

Diabetic skin lesions 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.

Please note the following particular risk of lactic acidosis.

Due to the metformin component, Jentadueto 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, prolonged fasting or alcohol intake, body fluid deficit (dehydration) due to severe diarrhoea or vomiting, liver problems and any medical conditions in which a region of the body is deprived with a lack of oxygen supply (such as acute severe heart diseases). It is important to you to comply with your medication intake, dietary instructions and regular exercise program because this can reduce the risk of lactic acidosis. The onset of lactic acidosis can be subtle and the symptoms can be non-specific such as vomiting, bellyache (abdominal pain) with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heart beat.

If you experience some of these symptoms, you should seek immediately medical attention, as lactic acidosis may lead to coma. Stop taking Jentadueto immediately and contact a doctor or the nearest hospital straight away.

Children and adolescents

This medicine is not recommended for use in children and adolescents under 18 years.

Other medicines and Jentadueto

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

In particular, you should tell your doctor if you are using the following medicines including those containing any of the active substances listed below:

- carbamazepine, phenobarbital or phenytoin. These may be used to control fits (seizures) or chronic pain.
- cimetidine, a medicine used to treat stomach problems.
- 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).
- medicines which increase urine production (diuretics).
- bronchodilators (β-sympathomimetics) for the treatment of bronchial asthma.
- iodinated contrast agents (which you may receive while having X-ray) or alcohol-containing medicines, see ‘Warnings and precautions’.

Jentadueto with alcohol

Avoid consumption of alcohol and medicinal products containing alcohol when taking Jentadueto. There is an increased risk of lactic acidosis following excessive alcohol consumption (particularly in the case of fasting, malnutrition, or liver disease) due to the active substance metformin.

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 Jentadueto 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
Jentadueto has no or negligible influence on the ability to drive and use machines.

However, taking Jentadueto 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.

3. How to take Jentadueto

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 Jentadueto 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 Jentadueto 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 Jentadueto 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 Jentadueto 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.

Sometimes you may need to stop taking your medicine for a short time. Talk to your doctor for instructions if you:

- have a condition that may be associated with dehydration (large loss of body fluids) such as being sick with severe vomiting, diarrhoea or fever, or if you drink fluids a lot less than normal.
- plan to have surgery.
- are due to get an injection of dye or contrast agent as part of an X-ray.

If you take more Jentadueto than you should

If you take more Jentadueto 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, stomach ache with muscle cramps, a general feeling of not being well with severe tiredness, and difficulty in breathing. Further symptoms are reduced body temperature and heart beat. **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 4). Take the medicine pack with you.**

If you forget to take Jentadueto

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 Jentadueto

Keep taking Jentadueto 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 Jentadueto 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) is an identified side effect for the combination of Jentadueto plus sulphonylurea and for the combination Jentadueto plus insulin.

Very rarely patients taking metformin (one of the active substances of Jentadueto) have experienced a serious condition called **lactic acidosis** (too much lactic acid in your blood). This is more common in people whose kidneys are not working properly. Stop taking Jentadueto and see a doctor straight away if you notice any of the following symptoms in combination:

- feeling sick (nausea) or being sick (vomiting), abdominal pain, severe weakness, muscular cramps, unexplained weight loss, rapid breathing, and feeling cold or uncomfortable.

Some patients have experienced inflammation of the pancreas (pancreatitis; frequency not known, frequency cannot be estimated from the available data). STOP taking Jentadueto 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 Jentadueto include:
Some patients have experienced allergic reactions (frequency rare), which may be serious, including wheezing and shortness of breath (bronchial hyperreactivity; frequency uncommon). 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 Jentadueto 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 Jentadueto:

- Common (may affect 1 in 10 people): diarrhoea
- Uncommon (may affect up to 1 in 100 people): inflamed nose or throat (nasopharyngitis), cough, loss of appetite (decreased appetite), feeling sick (nausea) or being sick (vomiting), blood enzyme increase (amylase increase), itching (pruritus)
- Frequency not known: blistering of skin (bullous pemphigoid)

Side effects when taking linagliptin alone:

All side effects of linagliptin alone are listed for Jentadueto.

Some patients have experienced the following side effects while taking Jentadueto with insulin

- Uncommon (may affect up to 1 in 100 people): liver function disorders, constipation

Please refer to the Package Leaflet for insulin for additional information.

Side effects when taking metformin alone, that were not described for Jentadueto:

- Very common (may affect more than 1 in 10 people): abdominal pain
- Common (may affect up to 1 in 10 people): a metallic taste (taste disturbance)
- Very rare (may affect up to 1 in 10,000 people): decreased vitamin B12 levels, hepatitis (a problem with your liver), skin reaction as redness of the skin (erythema, rash) and urticaria

Reporting of side effects

If you get any of the 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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Website: www.hpra.ie
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ADR Reporting
The Medicines Authority
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203 Level 3, Rue D’Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Jentadueto

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

This medicine does not require any special temperature storage conditions.

Blister: Store in the original package in order to protect from moisture.

Bottle: Keep the bottle tightly closed in order to protect from moisture.

Do not use this medicine if the package 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 Jentadueto contains

- The active substances are linagliptin and metformin.
 - Each Jentadueto 2.5 mg/850 mg film-coated tablet contains 2.5 mg of linagliptin and 850 mg of metformin hydrochloride.
 - Each Jentadueto 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: arginine, copovidone, magnesium stearate, maize starch, silica, colloidal anhydrous.
 - Film coating: hypromellose, titanium dioxide (E171), talc, propylene glycol.
- Jentadueto 2.5 mg/850 mg film-coated tablets also contain iron oxide red (E172) and iron oxide yellow (E172).
- Jentadueto 2.5 mg/1,000 mg film-coated tablets also contain iron oxide red (E172).

What Jentadueto looks like and contents of the pack

Jentadueto 2.5 mg/850 mg are oval, biconvex, light orange, film-coated tablets (tablets). They have “D2/850” debossed on one side and the Boehringer Ingelheim logo debossed on the other.

Jentadueto 2.5 mg/1,000 mg are oval, biconvex light pink film-coated tablets (tablets). They have “D2/1000” debossed on one side and the Boehringer Ingelheim logo debossed on the other.

Jentadueto is available in perforated unit dose blisters with 10 x 1, 14 x 1, 28 x 1, 30 x 1, 56 x 1, 60 x 1, 84 x 1, 90 x 1, 98 x 1, 100 x 1 and 120 x 1 film-coated tablets and multipacks containing 120 x 1 (2 packs of 60 x 1), 180 x 1 (2 packs of 90 x 1) and 200 x 1 (2 packs of 100 x 1) film-coated tablets.

Jentadueto is also available in HDPE bottles with plastic screw cap and a silica gel desiccant. Bottles contain 14, 60 or 180 film-coated tablets.

Not all pack sizes may be marketed in your country.

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This leaflet was last revised in 04/2016.

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu/>.