

# 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:

- 1.What Jentadueto is and what it is used for
- 2.What you need to know before you take Jentadueto
- 3.How to take Jentadueto
- 4.Possible side effects
- 5.How to store Jentadueto
- 6.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.

## 2. What you need to know before you take Jentadueto

### Do not take Jentadueto

- if you are allergic to linagliptin or metformin or any of the other ingredients of this medicine (listed in section 6).
- if you have problems with your kidneys.
- if you have a severe infection or are dehydrated.
- if you ever had a diabetic coma.
- if you have diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting).
- 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 every day or only from time to time).

Do not take Jentadueto 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 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).
- if you experience any of the following symptoms in combination: feeling cold or uncomfortable, severe nausea or vomiting, abdominal pain, severe asthenia, unexplained weight loss, muscular cramps, or rapid breathing. Metformin hydrochloride, one of the ingredients in Jentadueto, can cause a rare but serious side effect called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital. If you experience some of the symptoms of lactic acidosis stop taking Jentadueto and consult a doctor immediately. Lactic acidosis may also be caused by excessive alcohol intake or prolonged fasting.
- 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.

### 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.

### 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 than you should, talk to a doctor straight away.

### 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 Jentaduetto include:**

Some patients have experienced allergic reactions (frequency rare), which may be serious, including wheezing and shortness of breath (bronchial hyperreactivity; frequency rare). 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 Jentaduetto 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 Jentaduetto:

- Uncommon (may affect up to 1 in 100 people): inflamed nose or throat (nasopharyngitis), cough, loss of appetite (decreased appetite), diarrhoea, feeling sick (nausea) or being sick (vomiting), blood enzyme increase (amylase increase), itching (pruritus)

**Side effects when taking linagliptin alone:**

All side effects of linagliptin alone are listed for Jentaduetto.

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

- Common (may affect up to 1 in 10 people): liver function disorders
- Uncommon (may affect up to 1 in 100 people): constipation

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

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

- 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 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](http://www.mhra.gov.uk/yellowcard)

**Ireland**

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Fax: +353 1 6762517  
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**Malta**

ADR Reporting  
The Medicines Authority  
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203 Level 3, Rue D'Argens  
GŻR-1368 Gżira  
Website: [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)  
e-mail: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

**5. How to store Jentaduetto**

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 Jentaduetto contains**

- The active substances are linagliptin and metformin.
  - Each Jentaduetto 2.5 mg/850 mg film-coated tablet contains 2.5 mg of linagliptin and 850 mg of metformin hydrochloride.
  - Each Jentaduetto 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
- Jentaduetto 2.5 mg/850 mg film-coated tablets also contain iron oxide red (E172) and iron oxide yellow (E172).
- Jentaduetto 2.5 mg/1,000 mg film-coated tablets also contain iron oxide red (E172).

**What Jentaduetto looks like and contents of the pack**

Jentaduetto 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.

Jentaduetto 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.

Jentaduetto 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.

Jentaduetto 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.

**Marketing Authorisation Holder**

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

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