Package leaflet: Information for the patient

Jentadueto® 2.5 mg / 850 mg film-coated tablets
Jentadueto® 2.5 mg / 1,000 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 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'. 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, empagliflozin, 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 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 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 'Jentadueto with alcohol').

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 this condition.
- 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 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 Jentadueto.

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 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, 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, 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 Jentadueto 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 Jentadueto 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
- 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 Jentadueto during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Jentadueto.

During treatment with Jentadueto, 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.

Other medicines and Jentadueto
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 Jentadueto before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with Jentadueto.

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 Jentadueto. 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.

Jentadueto with alcohol
Avoid excessive alcohol intake while taking Jentadueto 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 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.

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 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 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 (may affect more than 1 in 10 people)) is an identified side effect for the combination of Jentadueto plus sulphonylurea and for the combination Jentadueto plus insulin.

Jentadueto 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 Jentadueto 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 1000 people).
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 (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 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 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 Jentadueto with insulin
- Uncommon: liver function disorders, constipation

Side effects when taking metformin alone, that were not described for Jentadueto:
- 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 hydrochloride.
- 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 contains iron oxide red (E172) and iron oxide yellow (E172).
    Jentadueto 2.5 mg/1,000 mg film-coated tablets also contains 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), 180 x 1 (3 packs of 60 x 1) and 200 x 1 (2 packs of 100 x 1) film-coated tablets.

Jentadueto is also available in plastic 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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Manufacturer

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