

Linagliptin / Metformin hydrochloride (2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg)

What is in this leaflet

1. What TRAJENTA DUO is used for
2. How TRAJENTA DUO works
3. Before you use TRAJENTA DUO
4. How to use TRAJENTA DUO
5. While you are using it
6. Side effects
7. Storage and Disposal of TRAJENTA DUO
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of revision
12. Serial number

1. What TRAJENTA DUO is used for

The name of your tablet is Trajenta Duo. 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.

2. How TRAJENTA DUO 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'.

Type 2 diabetes mellitus 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.

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. Trajenta Duo can be used alone or with certain other medicines for diabetes like sulphonylureas or insulin.

3. Before you use TRAJENTA DUO

- When you must not use it

- if you are allergic to linagliptin or metformin or any of the other

ingredients of this medicine (listed in section *ingredients*).

- if you have severely reduced kidneys function.
- if you have uncontrolled diabetes, with, for example, severe hyperglycaemia (high blood glucose), nausea, vomiting, diarrhea, 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.
- 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.
- if you are treated for acute heart failure or have recently had a heart attack, or have severe problems with your circulation (such as shock) or having breathing difficulties. This may lead to a lack in oxygen supply to tissue which can put you at risk for lactic acidosis.
- if you have liver problems.
- if you drink alcohol to excess, either every day or only from time to time (see section "Trajenta Duo with alcohol").

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

Risk of lactic acidosis

Due to the metformin component, Trajenta Duo 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 Trajenta Duo 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 Trajenta Duo 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 Trajenta Duo during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with Trajenta Duo.

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

- Before you start use it

Talk to your doctor, pharmacist or nurse before taking Trajenta Duo

- if you have type 1 diabetes (your body does not produce any insulin).

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

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.

- Taking other medicines

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

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 Trajenta Duo. 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.
- 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).
- bronchodilators (β-sympathomimetics) for the treatment of bronchial asthma.
- alcohol-containing medicines.

Trajenta Duo with alcohol

Avoid excessive alcohol intake while taking Trajenta Duo since this may increase the risk of lactic acidosis.

4. How to use TRAJENTA DUO

- How much to use

The amount of Trajenta Duo 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.

- 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.

- When to use it

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 long to use it

Continue to take Trajenta Duo 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 Trajenta Duo 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 Trajenta Duo 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 forget to use it

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 use too much (overdose)

If you take more Trajenta Duo 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. Take the medicine pack with you.

5. While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Trajenta Duo.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Trajenta Duo to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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.

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 Trajenta Duo 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

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

However, taking Trajenta Duo 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.

6. Side effects

Like all medicines, TRAJENTA DUO can cause side effects, although not everybody gets them.

Some symptoms need immediate medical attention

You should stop taking Trajenta Duo 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 Trajenta Duo plus insulin.

Trajenta Duo may cause a very rare (may affect up to 1 user in 10,000), but very serious side effect called lactic acidosis (see section 'Risk of lactic acidosis'). If this happens you must stop taking Trajenta Duo 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 not known, frequency cannot be estimated from the available data).

STOP taking Trajenta Duo 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 Trajenta Duo 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 Trajenta Duo 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 Trajenta Duo:

- Common (may affect 1 in 10 people): diarrhoea, blood enzyme increase (lipase increase), 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.
- 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)
- Rare (may affect up to 1 in 1,000 people): blistering of skin (bullous pemphigoid), inflammation of pancreas (pancreatitis)

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Reporting of side effects

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nppra.gov.my [Consumer → Reporting Side Effects of Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of TRAJENTA DUO

- Storage

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

Do not store above 30°C.

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

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

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

Trajenta Duo 2.5 mg/500 mg are oval, biconvex, light yellow, film-coated tablets (tablets). They have "D2/500" debossed on one side and the Boehringer Ingelheim logo debossed on the other.

Trajenta Duo 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.

Trajenta Duo 2.5 mg/1000 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.

Trajenta Duo is available in cartons containing 60 film-coated tablets in a HDPE bottle.

- Ingredients

- Active ingredient(s):

- The active substances are linagliptin and metformin.
- Each Trajenta Duo 2.5 mg/500 mg film-coated tablet contains 2.5 mg of linagliptin and 500 mg of metformin hydrochloride.
- Each Trajenta Duo 2.5 mg/850 mg film-coated tablet contains 2.5 mg of linagliptin and 850 mg of metformin hydrochloride.
- Each Trajenta Duo 2.5 mg/1000 mg film-coated tablet contains 2.5 mg of linagliptin and 1000 mg of metformin hydrochloride.

- Inactive ingredients:

- Tablet core: arginine, copovidone, magnesium stearate, maize starch, silica, colloidal anhydrous.
- Film coating: hypromellose, titanium dioxide (E171), talc, propylene glycol.
- Trajenta Duo 2.5 mg/500 mg film-coated tablets also contain iron oxide yellow (E172).
- Trajenta Duo 2.5 mg/850 mg film-coated tablets also contain iron oxide red (E172) and iron oxide yellow (E172).
- Trajenta Duo 2.5 mg/1000 mg film-coated tablets also contain iron oxide red (E172).

- MAL number(s):

Trajenta Duo 2.5 mg/500mg:

MAL13025056AZ

Trajenta Duo 2.5 mg/850mg:

MAL13025057AZ

Trajenta Duo 2.5 mg/1000mg:

MAL13025058AZ

9. Manufacturer

Boehringer Ingelheim Promeco, S.A de C.V.

Calle del Maíz No. 49,

Col. Barrio Xaltocan, C.P. 16090

Xochimilco, Mexico City, Mexico.

For

Boehringer Ingelheim International GmbH

Ingelheim am Rhein

Germany

10. Product Registration Holder

Boehringer Ingelheim (Malaysia) Sdn. Bhd.

Level 23A, Mercu Aspire,
No. 3, Jalan Bangsar, KL Eco City,
59200 Kuala Lumpur, Malaysia.

11. Date of revision

06/03/2026

12. Serial number

NPRA (R1/1) 17102022/289