PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAME (and dosage form)

Trajenta®

film-coated tablets

5 mg linagliptin

Read all of this leaflet carefully before you start taking TRAJENTA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- TRAJENTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT TRAJENTA FILM-COATED TABLETS CONTAIN

The active substance is linagliptin. Each film-coated tablet contains linagliptin 5 mg.
The other (inactive) ingredients are copovidone, magnesium stearate, maize starch, mannitol, Opadry® pink, starch pregelatinised.
Sugar (sucrose) and lactose free.

2. WHAT TRAJENTA FILM-COATED TABLETS ARE USED FOR

TRAJENTA contains the active substance linagliptin which belongs to a group of medicines called 'oral anti-diabetics', which are medicines taken by mouth to treat high blood sugar levels. They work by helping the body reduce the level of sugar in your blood.

TRAJENTA is used for 'type 2 diabetes' in adults to improve blood sugar control, together with diet and exercise.

TRAJENTA may be used alone or together with other anti-diabetic medicines (for example, your doctor may prescribe TRAJENTA with other tablets to lower your blood sugar or together with insulin).

It is important to keep following the advice about diet and exercise that you have been given by your doctor or nurse.

3. BEFORE YOU TAKE TRAJENTA FILM-COATED TABLETS

Do not take TRAJENTA:

- if you are allergic (hypersensitive) to linagliptin or any of the other ingredients of TRAJENTA film-coated tablets.
- if you have pancreatitis (inflammation of the pancreas) or have had pancreatitis in the past.
- if you have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a serious complication of diabetes caused by increased ketones in

the blood and urine, with symptoms such as nausea, vomiting, abdominal pain, fruity odour to breath, lethargy, drowsiness, and shortness of breath).
- TRAJENTA is not recommended for children and adolescents under 18 years.

Take special care with TRAJENTA:
Talk to your doctor, pharmacist or nurse before taking TRAJENTA if you:
- are taking or using any other medicines to lower your blood sugar.
  If you are also taking another anti-diabetic medicine known as a 'sulphonylurea' (e.g. glimepiride, glipizide), your doctor may want to reduce your dose of sulphonylurea when you take it together with TRAJENTA in order to avoid low blood sugar.
- have had an allergic reaction in the past to any other medicine that you have taken to control the amount of sugar in your blood.

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.

If you encounter blistering of the skin, it may be a sign of a condition called 'bullous pemphigoid'. Your doctor may ask you to stop taking TRAJENTA.

Tell your healthcare provider right away if you have unexplained muscle pain, tenderness or weakness, and dark or discoloured urine. On rare occasion muscle problems, including muscle breakdown, can be serious and may cause kidney damage. The risk may be higher if you have abnormal kidney function or when taking other medicines such as 'statins' or colchicine.

Taking TRAJENTA with food and drink:
You can take TRAJENTA with or without food.

Pregnancy and breastfeeding:
Talk to your doctor before you take TRAJENTA if you are pregnant or plan to become pregnant. You should not take TRAJENTA if you are pregnant. It is unknown if TRAJENTA is harmful to the unborn child.

It is not known if TRAJENTA passes into human breast milk. If you are breastfeeding your baby do not take TRAJENTA.

Driving and using machinery:
Taking TRAJENTA in combination with medicines called sulphonylureas can cause blood sugar levels which are too low (hypoglycaemia), which may affect your ability to drive and use machines.
If you experience symptoms of low blood sugar such as trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion while taking TRAJENTA, do not drive or use machines, and contact your healthcare professional immediately.

Taking other medicines with TRAJENTA:
If you are taking other medicines on a regular basis, including prescription medicines or medicines bought over the counter and complementary or traditional medicines, the use

of TRAJENTA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

In particular, you should tell your doctor, pharmacist or healthcare professional if you are taking:

- medicines containing rifampicin. This is an antibiotic used to treat infections such as tuberculosis.
- other medicines that can lower your blood sugar.

4. HOW TO TAKE TRAJENTA FILM-COATED TABLETS

Follow your healthcare providers' directions carefully. Always take TRAJENTA tablets every day exactly as your doctor told you. Do not take more or less tablets and do not take them more often than recommended. You should check with your healthcare professional if you are not sure.

Take TRAJENTA by mouth once daily. The usual dose is one tablet (5 mg) once daily. TRAJENTA tablets are intended for maintenance (long-term) treatment.

Your doctor may prescribe TRAJENTA together with other anti-diabetic medicine. Remember to take all medicines as directed by your doctor to achieve the best results for your health.
Check your blood sugar as your healthcare professional tells you to.
If you have the impression that the effect of TRAJENTA is too strong, or too weak, talk to your doctor, pharmacist or nurse.

Do not share medicines prescribed for you with any other person.

If you take more TRAJENTA than you should:
In the event of overdosage or accidental intake, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take TRAJENTA:
If you forget to take a dose of TRAJENTA, 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 on the same day.

Effects when treatment with TRAJENTA is stopped:
Do not stop taking TRAJENTA without first consulting your doctor. Your blood sugar levels may increase when you stop taking TRAJENTA.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

5. POSSIBLE SIDE EFFECTS

TRAJENTA film-coated tablets can have side effects.
Not all side effects reported for TRAJENTA are included in this leaflet. Should you have any side effect that bothers you or does not go away, or if your general health worsens

while taking TRAJENTA, please consult your doctor, pharmacist or other healthcare professional as soon as possible for advice.

Some symptoms need immediate medical attention.
You should contact your doctor immediately if you experience:

- any sign of an allergic reaction (hypersensitivity) such as skin rash, hives, and swelling of the face, lips, tongue and throat that may cause difficulty in breathing or swallowing and wheezing and shortness of breath.
- symptoms of low blood sugar (hypoglycaemia) such as trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion. Low blood sugar is identified as a frequent side effect for the combination of TRAJENTA plus metformin and plus a sulphonylurea. Talk to your doctor or other healthcare professional about how to recognise, manage and prevent low blood sugar (hypoglycaemia).
- any symptoms of pancreatitis (inflammation of the pancreas) such as severe stomach pain which may radiate to the back, often with nausea and vomiting. Please refer to '**Do not take TRAJENTA**'.

Other side effects may include:

- stuffy or runny nose and sore throat (nasopharyngitis)
- cough
- blistering of the skin (bullous pemphigoid)
- severe skin reactions such as breakdown or erosion of the outer layer of the skin
- muscle pain, tenderness or weakness with dark or discoloured urine, which may be symptoms of rhabdomyolysis.

Some patients have experienced constipation while taking TRAJENTA together with insulin.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

6. STORING AND DISPOSING OF TRAJENTA FILM-COATED TABLETS

Store at or below 30 °C.
Keep out of the reach and sight of children.

Do not take TRAJENTA after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.
Do not take TRAJENTA if the package is damaged or shows signs of tampering.

Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF TRAJENTA FILM-COATED TABLETS

Aluminium blister packs of 30 tablets. Printed cardboard cartons contain 3 blister cards of 10 tablets each.

8. IDENTIFICATION OF TRAJENTA FILM-COATED TABLETS

Light red, round, biconvex, bevel-edged film-coated tablets, one side debossed with BI company symbol, the other side debossed with ‘D5’.

9. REGISTRATION NUMBER

45/21.2/0557

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 15 August 2013
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