

Package leaflet: Information for the user

Linagliptin Clonmel 5 mg film-coated tablets

Linagliptin

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 Linagliptin Clonmel is and what it is used for
2. What you need to know before you take Linagliptin Clonmel
3. How to take Linagliptin Clonmel
4. Possible side effects
5. How to store Linagliptin Clonmel
6. Contents of the pack and other information.

1. What Linagliptin Clonmel is and what it is used for

Linagliptin Clonmel contains the active substance linagliptin, which belongs to a group of medicines called “oral anti-diabetics”. Oral anti-diabetics are used to treat high blood sugar levels. They work by helping the body reduce the level of sugar in your blood.

Linagliptin Clonmel is used for ‘type 2 diabetes’ in adults, if the disease cannot be adequately controlled with one oral anti-diabetic medicine (metformin or sulphonylureas) or diet and exercise alone. Linagliptin Clonmel may be used together with other anti-diabetic medicines e.g. metformin, sulphonylureas (e.g. gliclazide, glibenclamide), empagliflozin, or insulin.

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

2. What you need to know before you take Linagliptin Clonmel

DO NOT take Linagliptin Clonmel

- if you are allergic to linagliptin or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Linagliptin Clonmel if you:

- have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar, rapid weight loss, nausea or vomiting). Linagliptin Clonmel should not be used to treat these conditions
- are taking an anti-diabetic medicine known as a ‘sulphonylurea’ (e.g. gliclazide, glibenclamide), your doctor may want to reduce your dose of sulphonylurea when you take it together with Linagliptin Clonmel in order to avoid your blood sugar going too low
- have had allergic reactions to any other medicines that you take to control the amount of sugar in your blood
- have or have had a disease of the pancreas

If you have symptoms of acute pancreatitis, like persistent, severe stomach ache (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 Linagliptin Clonmel.

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

Linagliptin Clonmel is not recommended for children and adolescents under 18 years.

Other medicines and Linagliptin Clonmel

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 medicines containing any of the following active substances:

- 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

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.

It is unknown if linagliptin is harmful to the unborn child. Therefore, it is preferable to avoid using Linagliptin Clonmel if you are pregnant.

It is not known if linagliptin passes into human breast milk. A decision must be made by your doctor whether to discontinue breast-feeding or to discontinue/abstain from Linagliptin Clonmel therapy.

Driving and using machines

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

Taking Linagliptin Clonmel in combination with medicines called sulphonylureas and/or insulin can cause too low blood sugar levels (hypoglycaemia), which may affect your ability to drive and use machines or work without safe foothold. However, more frequent blood glucose testing might be recommended to minimise the risk for hypoglycaemia, especially when Linagliptin Clonmel is combined with sulphonylurea and/or insulin.

3. How to take Linagliptin Clonmel

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose of Linagliptin Clonmel is one 5 mg tablet once a day.

Method of administration

To be taken by mouth. You can take Linagliptin Clonmel with or without food.

Your doctor may prescribe Linagliptin Clonmel together with another oral anti-diabetic medicine. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

If you take more Linagliptin Clonmel than you should

If you take more Linagliptin Clonmel than you should, talk to a doctor immediately.

If you forget to take Linagliptin Clonmel

- if you forget to take a dose of Linagliptin Clonmel, 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

If you stop taking Linagliptin Clonmel

Do not stop taking Linagliptin Clonmel without first consulting your doctor. Your blood sugar levels may increase when you stop taking Linagliptin Clonmel.

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

STOP taking Linagliptin Clonmel and contact a doctor immediately if you notice any of the following serious side effects:

Very common (may affect more than 1 in 10 people)

- symptoms of low blood sugar: trembling, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion (hypoglycaemia)
Hypoglycaemia is an identified side effect when linagliptin is taken together with metformin and a sulphonylurea.

Rare (may affect up to 1 in 1,000 people)

- 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)

STOP taking Linagliptin Clonmel and contact a doctor immediately if you notice any of the following signs or symptoms of an allergic reaction:

Uncommon (may affect up to 1 in 100 people)

- allergic reactions (hypersensitivity) including wheezing and shortness of breath (bronchial hyperreactivity)
- rash

Rare (may affect up to 1 in 1,000 people)

- hives (urticaria)
- swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing (angioedema)

⇒ Your doctor may prescribe a medicine to treat your allergic reaction and a different medicine for your diabetes.

Other side effects

Common (may affect up to 1 in 10 people)

- level of lipase in the blood increased

Uncommon (may affect up to 1 in 100 people)

- inflamed nose or throat (nasopharyngitis)
- cough
- constipation (in combination with insulin)
- level of amylase in the blood increased

Rare (may affect up to 1 in 1,000 people)

- blistering of skin (bullous pemphigoid)

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 via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Linagliptin Clonmel

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

This medicine does not require any special storage conditions.

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 Linagliptin Clonmel contains

The active substance is linagliptin. Each film-coated tablet contains 5 mg of linagliptin.

The other ingredients are:

- Tablet core: Cellulose microcrystalline, hypromellose 2208, crospovidone type A, silica colloidal anhydrous, magnesium stearate
- Film coating: Hypromellose 2910, talc, titanium dioxide (E171), macrogol (type 3350), iron oxide red (E172)

What Linagliptin Clonmel looks like and contents of the pack

Linagliptin Clonmel 5 mg tablets are greyish red, round, biconvex film-coated tablets.

The tablets (with dimensions of 8 mm x 5 mm) are supplied in blisters manufactured of a combined oPA-Alu-PVC form foil sealed with an aluminium foil.

Pack sizes:

Blisters: 10, 28, 30, 56, 90, 100 tablets.

Unit-dose Blisters: 10x1, 28x1, 30x1, 56x1, 90x1, 100x1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Linagliptin STADA 5 mg Filmtabletten
Belgium:	Linagliptin EG 5mg filmomhulde tabletten
Czech Republic:	Linagliptin STADA
Denmark:	Linagliptin STADA
Finland:	Linagliptin STADA 5 mg kalvopäällysteiset tabletit
Hungary:	Linagliptin Stada 5 mg filmtabletta
Iceland:	Linagliptin STADA filmuhúðaðar töflur
Ireland:	Linagliptin Clonmel 5 mg film-coated tablets
Italy:	Linagliptin EG
Luxembourg:	Linagliptin EG 5mg comprimés pelliculés
Portugal:	Linagliptina Ciclum
Spain:	Linagliptina STADA 5mg comprimidos recubiertos con película EFG
Slovakia:	Linagliptin STADA 5mg filmom obalené tablety

Slovenia: Linagliptin STADA 5 mg filmsko obložene tablete
Sweden: Linagliptin STADA 5 mg filmdragerade tabletter

This leaflet was last revised in April 2021.