

## **Package leaflet: Information for the patient**

### **Linezolid Clonmel 600mg Film-coated Tablets**

Active substance: Linezolid

**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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Linezolid Clonmel is and what it is used for**

Linezolid Clonmel contains the active substance linezolid.

Linezolid Clonmel is an antibiotic of the oxazolidinones group that works by stopping the growth of certain bacteria (germs) that cause infections. It is used to treat pneumonia and some infections in the skin or under the skin. Your doctor will have decided if Linezolid Clonmel is suitable to treat your infection.

#### **2. What you need to know before you take Linezolid Clonmel**

Contact your doctor if you are not sure if you belong to a patient group described below.

#### **Do not take Linezolid Clonmel if you are**

- allergic to linezolid or any of the other ingredients of this medicine (listed in section 6).
- taking or have taken within the last 2 weeks any medicines known as monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease.
- breastfeeding. This is because it passes into breast milk and could affect the baby.

Linezolid Clonmel must not be used if you answer yes to any of the following questions. In this case tell your doctor as he/she will need to check your general health and your blood pressure before and during your treatment, or may decide that another treatment is better for you.

Ask your doctor if you are not sure whether these categories apply to you.

- Do you have high blood pressure?
- Have you been diagnosed with an overactive thyroid?
- Do you have a tumour of the adrenal glands (phaeochromocytoma) or carcinoid syndrome (caused by tumours of the hormone system with symptoms of diarrhoea, flushing of the skin, wheezing)?
- Do you suffer from manic depression, schizoaffective disorder, mental confusion or other mental problems?
- Are you taking any of the following medicines?
  - decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine
  - medicines used to treat asthma such as salbutamol, terbutaline, fenoterol

- antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors) for example amitriptyline, ciproamil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline
- medicines used to treat migraine such as sumatriptan and zolmitriptan
- medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine)
- medicines which increase your blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine
- medicines used to treat moderate to severe pain, such as pethidine
- medicines used to treat anxiety disorders, such as buspirone
- an antibiotic called rifampicin

### Warnings and precautions

Talk to your doctor before using Linezolid Clonmel if you

- bruise and bleed easily
- are anaemic
- are prone to getting infections
- have a history of seizures
- have liver problems or kidney problems particularly if you have dialysis
- have diarrhoea

Tell your doctor immediately if during treatment you suffer from

- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- you may develop diarrhoea while taking or after taking antibiotics, including Linezolid Clonmel. If this becomes severe or persistent or you notice that your stools contain blood or mucus, you should stop taking Linezolid Clonmel immediately and consult your doctor. In this situation, you should not take medicines that stop or slow bowel movement.
- recurrent nausea or vomiting, abdominal pain or over breathing

### Children and adolescents

This medicine is not recommended to treat children and adolescents under the age of 18 because efficacy and safety have not been established for this age group.

### Other medicines and Linezolid Clonmel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

There is a risk that Linezolid Clonmel may sometimes interact with certain other medicines to cause side effects such as changes in blood pressure, temperature or heart rate.

**Tell your doctor if you are taking or have taken within the last 2 weeks** the following medicines as Linezolid Clonmel **must not** be taken if you are already taking these medicines or have taken them recently. (See also Section 2 above 'Do not take Linezolid Clonmel if you are').

- monoamine oxidase inhibitors (MAOIs for example phenelzine, isocarboxazid, selegiline, moclobemide). These may be used to treat depression or Parkinson's disease.

Also tell your doctor if you are taking the following medicines. Your doctor may still decide to give you Linezolid Clonmel, but will need to check your general health and your blood pressure before and during your treatment. In other cases, your doctor may decide that another treatment is better for you.

- Decongestant cold or flu remedies containing pseudoephedrine or phenylpropanolamine.
- Some medicines used to treat asthma such as salbutamol, terbutaline, fenoterol.
- Certain antidepressants known as tricyclics or SSRIs (selective serotonin reuptake inhibitors). There are many of these, including amitriptyline, ciproamil, clomipramine, dosulepin, doxepin, fluoxetine, fluvoxamine, imipramine, lofepramine, paroxetine, sertraline.
- Medicines used to treat migraine such as sumatriptan and zolmitriptan.

- Medicines used to treat sudden, severe allergic reactions such as adrenaline (epinephrine).
- Medicines which increase your blood pressure, such as noradrenaline (norepinephrine), dopamine and dobutamine.
- Medicines used to treat moderate to severe pain, such as pethidine.
- Medicines used to treat anxiety disorders, such as buspirone.
- Medicines that stop blood clotting, such as warfarin.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Linezolid Clonmel with food, drink and alcohol**

You can take Linezolid Clonmel either before, during or after a meal.

Avoid eating large amounts of mature cheese, yeast extracts, or soya bean extracts e.g. soy sauce and drinking alcohol, especially draught beers and wine. This is because this medicine may react with a substance called tyramine which is naturally present in some foods to cause an increase in your blood pressure.

If you develop a throbbing headache after eating or drinking, tell your doctor or pharmacist immediately.

### **Pregnancy and breast-feeding**

The effect of Linezolid Clonmel in pregnant women is not known. Therefore it should not be taken in pregnancy unless advised by your doctor.

You should not breastfeed when taking Linezolid Clonmel because it passes into breast milk and could affect the baby.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

### **Driving and using machines**

Linezolid Clonmel may make you feel dizzy or experience problems with your vision. If this happens, do not drive or operate any machinery. Remember that if you are unwell your ability to drive or operate machinery may be affected.

### **Linezolid Clonmel contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## **3. How to take Linezolid Clonmel**

### **Adults**

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

The recommended dose is one tablet (600 mg linezolid) twice daily (every twelve hours). Swallow the tablet whole with some water.

If you are on kidney dialysis, you should take Linezolid Clonmel after dialysis.

A course of treatment usually lasts 10 to 14 days but can last up to 28 days. The safety and effectiveness of this medicine have not been established for treatment periods longer than 28 days. Your doctor will decide how long you should be treated.

While you are taking Linezolid Clonmel, your doctor should perform regular blood tests to monitor your blood count.

Your doctor should monitor your eyesight if you take Linezolid Clonmel for more than 28 days.

#### **Use in children and adolescents**

Linezolid Clonmel is not normally used to treat children and adolescents (under 18 years old).

#### **If you take more Linezolid Clonmel than you should**

Tell your doctor or pharmacist immediately.

#### **If you forget to take Linezolid Clonmel**

Take the forgotten tablet as soon as you remember. Take the next tablet 12 hours after this and continue taking your tablets every 12 hours. Do not take a double dose to make up for a forgotten tablet.

#### **If you stop using Linezolid Clonmel**

Unless your doctor instructs you to stop treatment, it is important to continue taking Linezolid Clonmel.

If you stop and your original symptoms come back tell your doctor or pharmacist immediately.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

**Tell your doctor, nurse or pharmacist immediately** if you notice any of these side effects during your treatment with Linezolid Clonmel:

- skin reactions such as red sore skin and flaking (dermatitis), rash, itching, or swelling, particularly around the face and neck. This may be the sign of an allergic reaction and it may be necessary for you to stop taking Linezolid Clonmel.
- problems with your vision such as blurred vision, changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted.
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in very rare circumstances may develop into complications that are life-threatening.
- recurrent nausea or vomiting, abdominal pain or over breathing.
- fits or seizures have been reported with Linezolid Clonmel. You should let your doctor know if you experience agitation, confusion, delirium, rigidity, tremor, incoordination and seizure while also taking antidepressants known as SSRI's (see section 2).

Numbness, tingling or blurred vision have been reported by patients who have been given Linezolid Clonmel for more than 28 days. If you experience difficulties with your vision you should consult your doctor as soon as possible.

#### **Other side effects include:**

##### **Common side-effects (may affect up to 1 in 10 people):**

- Fungal infections especially vaginal or oral "thrush"
- Headache
- Metallic taste in the mouth
- Diarrhoea, nausea or vomiting
- Changes in some blood test results including those measuring your kidney or liver function or blood sugar levels
- Unexplained bleeding or bruising, which may be due to changes in the numbers of certain cells in the blood which may affect blood clotting or lead to anaemia

##### **Uncommon side-effects (may affect up to 1 in 100 people):**

- Inflammation of the vagina or genital area in women
- Changes in numbers of certain cells in the blood which may affect your ability to fight infection
- Difficulty in sleeping
- Dizziness, sensations such as tingling or feeling numb
- Blurred vision
- “Ringing” in the ears (tinnitus)
- Increased blood pressure, inflammation of the veins
- Indigestion, stomach pain, constipation
- Dry or sore mouth, swollen, sore, or discoloured tongue
- Skin rash
- A need to urinate more often
- Fever or chills, aches and pains
- Feeling tired or thirsty
- Inflammation of the pancreas
- Increased sweating
- Changes in proteins, salts or enzymes in the blood which measure kidney or liver function
- Reduction in the numbers of cells in the blood which fight against infection

**Rare side-effects (may affect up to 1 in 1,000 people):**

- Changes in heart rate (e.g. increase rate)
- Transient ischaemic attacks (temporary disturbance of blood flow to the brain causing short term symptoms such as loss of vision, leg and arm weakness, slurring of speech and loss of consciousness)
- Kidney failure

**The following side effects have also been reported (frequency not known):**

- Serotonin syndrome (symptoms include fast heart rate, confusion, abnormal sweating, hallucinations, involuntary movements, chills and shivering)
- Lactic acidosis (symptoms include recurrent nausea and vomiting, abdominal pain, overbreathing)
- Severe skin disorders
- Convulsions
- Superficial tooth discolouration, removable with professional dental cleaning (manual descaling)
- Alopecia (hair loss)
- Hyponatraemia (low blood sodium levels)
- Changes in colour vision, difficulty in seeing detail or if your field of vision becomes restricted

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Linezolid 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. The expiry date refers to the last day of that month.

This medicinal product 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 Linezolid Clonmel contains

- The active substance in this medicine is called linezolid. Each tablet contains 600 mg linezolid.
- The other ingredients are silicified microcrystalline cellulose (cellulose microcrystalline, silica, colloidal anhydrous), sodium starch glycolate (type A), cellulose, microcrystalline, povidone K90, magnesium stearate.

The film-coating contains hypromellose, propylene glycol, titanium dioxide (E171), talc.

### **What Linezolid Clonmel looks like and contents of the pack**

Linezolid Clonmel 600 mg film-coated tablets are oblong, biconvex, white to off-white film-coated tablets.

Linezolid Clonmel tablets are packed in cartons containing PVC/PVdC-Aluminium foil blisters containing 1, 10, 20, 30, 40, 60, 80, 100, 120 and 200 film-coated 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:

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

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

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

Germany: Linezolid STADA 600 mg Filmtabletten  
Ireland: Linezolid Clonmel 600 mg film-coated tablets  
Portugal: Linezolida Stada

**This leaflet was last revised in May 2018.**