

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

**APPROVED PATIENT INFORMATION LEAFLET**

**S3**

**GIROTEC 25 mg TABLETS**

**GIROTEC mg TABLETS**

**GIROTEC 100 mg TABLETS**

**GIROTEC 200 mg TABLETS**

Lamotrigine

**Read all of this leaflet carefully before you start taking GIROTEC.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **GIROTEC 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 GIROTEC CONTAINS**

The active substance is lamotrigine.

**GIROTEC 25 mg TABLETS:** Each uncoated tablet contains lamotrigine 25 mg.

Contains sweetener: sucralose 2.0 mg.

**GIROTEC 50 mg TABLETS:** Each uncoated tablet contains lamotrigine 50 mg.

Contains sweetener: sucralose 4.0 mg.

**GIROTEC 100 mg TABLETS:** Each uncoated tablet contains lamotrigine 100 mg.

Contains sweetener: sucralose 8.0 mg.

**GIROTEC200 mg TABLETS:** Each uncoated tablet contains lamotrigine 200 mg.

Contains sweetener: sucralose 16.0 mg.

The other ingredients are black currant flavour; cellulose, microcrystalline; magnesium carbonate; magnesium stearate; polacrillin potassium and povidone.

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

## 2. WHAT GIROTEC ARE USED FOR

**GIROTEC** belong to a group of medicines called antiepileptics. They are used to treat two conditions – epilepsy and bipolar disorder.

### EPILEPSY

- **For adults and children aged 12 years and over**

**GIROTEC** can be used on their own or with other medicines, to treat certain types of seizures in patients with epilepsy.

- **For children aged between 2 and 12 years**

**GIROTEC** can be used with other medicines, to treat certain types of seizures in patients with epilepsy. It is recommended that **GIROTEC** are not used on their own to treat epilepsy in children under 12 years of age.

**GIROTEC** can also be used with other medicines to treat the seizures that occur with a condition called Lennox-Gastaut Syndrome.

### BIPOLAR DISORDER

- **For adults 18 years of age and over**

**GIROTEC** are used to help prevent the mood episodes that occur in patients with bipolar disorder, mainly by preventing the depressive phases.

## 3. BEFORE YOU TAKE GIROTEC

### Do not take **GIROTEC**:

- If you are hypersensitive (allergic) to lamotrigine, or any of the other ingredients of **GIROTEC**.
- If you are pregnant or breastfeeding.
- If you have kidney or liver problems.
- If you are over the age of 65 years.

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

**Take special care with GIROTEC:**

- Some patients may experience severe seizures, which may lead to serious health problems, usually causing death.

If you experience a severe seizure while you are taking **GIROTEC**, see a doctor as soon as possible.

Your doctor may consider withdrawing **GIROTEC** therapy if worsening of seizure control occurs.

- If you have history of heart problems or heart surgery you may experience an abnormal heart beat that can cause serious harm
- While taking **GIROTEC** you may experience a persistent fever (one that is greater than 38 °C). Immediately seek medical attention if this happens.
- You may develop a rash while taking **GIROTEC**. These skin reactions are most likely to happen within the first 8 weeks of starting treatment. Although most patients who develop a rash have mild symptoms, some individuals may develop a serious (sometimes fatal i.e. causing death) skin reaction that requires hospitalisation. Scarring and deaths have been reported. Serious skin reactions occur more often in children than in adults.
- Rashes may be more likely to occur if you:
  - take **GIROTEC** in combination with another medicine called valproate
  - start on too high a dose
  - increase your dose too quickly
- It is not possible to predict whether a mild rash will develop into a more serious reaction.

**Therefore, if you develop any of these symptoms after you start taking GIROTEC, get a doctor's help straight away: skin rash, a high temperature (fever), swollen lymph glands, itching, swelling around your face, blood and liver problems, unexpected bleeding or bruising, flu-like symptoms or drowsiness.** A doctor should evaluate your condition and decide if you should continue taking **GIROTEC**.

- Patients with bipolar disorder can sometimes have thoughts of harming themselves or committing suicide. Call your doctor at once if you have any thoughts about suicide or hurting yourself.
- While you are taking **GIROTEC**, your doctor may decide to carry out tests on your liver, kidneys or blood.

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

- Never take more **GIROTEC** than your doctor tells you to.
- To stop taking **GIROTEC**, it is important that your dose is reduced gradually, over a period of 2 weeks. If you suddenly stop taking **GIROTEC** your epilepsy may come back or get worse.
- Since the effective dose for children depends on their body weight, the weight of a child must be monitored and the dose reviewed as weight changes occur.
- **GIROTEC should** be used cautiously in patients taking folate antagonists (medicines which interfere with folic acid metabolism).

#### **Taking GIROTEC with food and drink:**

- **GIROTEC can** be taken with or without food.

#### **Pregnancy and Breastfeeding:**

- The safe use of **GIROTEC during** pregnancy and breastfeeding has not been determined.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **GIROTEC**.

#### **Driving and using machinery:**

- **GIROTEC can** cause dizziness, drowsiness and blurred or double vision. Do not drive or operate machines if you are affected.

#### **Taking other medicines with GIROTEC:**

Always tell your healthcare professional if you are taking any other medicine

(This include complementary or traditional medicine)

Before taking **GIROTEC**, tell your doctor if you are using any of the following medicines:

- Phenytoin
- Carbamazepine
- Phenobarbitone
- Primidone

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

- Valproic acid
- Oral contraceptives (birth control pills) – If you are using an oral contraceptive and you notice any changes in your menstrual pattern, such as breakthrough bleeding or spotting between periods, tell your doctor.
- Rifampicin
- Lopinivir
- Ritonavir

If you are using any of the above medicines, you may not be able to take **GIROTEC**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

#### 4. HOW TO TAKE GIROTEC

Always take **GIROTEC exactly** as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **GIROTEC is** too strong or too weak, tell your doctor or pharmacist.

- Use **GIROTEC as** directed by your doctor.
- Do not increase your dose of **GIROTEC or** take more frequent doses than those indicated by your doctor.
- Your doctor will start you on a low dose, and gradually increase the dose over a few weeks until you reach a dose that works for you (called the effective dose).
- The dose you take will depend on your age and whether you are taking **GIROTEC with** other medicines.
- The usual effective dose of **GIROTEC for** adults and children aged over 12 years is between 100 mg and 400 mg each day.
- For children aged 2 to 12 years, the effective dose depends on their body weight – usually it's between 1 mg and 15 mg for each kilogram of the child's weight, up to a maximum of 400 mg daily.
- **GIROTEC should** not be given to patients aged under 18 years to treat bipolar disorder.

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

**If you take more GIROTEC than you should:**

- Symptoms of overdose may include sedation (having a soothing, calming or tranquilizing effect), clumsiness and lack of co-ordination, double vision, nausea and vomiting.
- If you have taken more **GIROTEC than** you should, you should be admitted to hospital and given appropriate treatment.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**If you forget to take GIROTEC:**

Do not take a double dose to make up for forgotten individual doses.

**5. POSSIBLE SIDE EFFECTS**

**GIROTEC can** have side effects.

**Allergic reaction or potentially serious skin reaction, get a doctor's help straight away.**

You may experience an allergic reaction or potentially serious skin reaction, which may develop into more serious, and even life-threatening problems if not treated.

Symptoms of these reactions include:

- skin rashes or redness
- angioedema (trouble in breathing, swelling of face, mouth, hands or feet)
- high temperature (fever), flu-like symptoms or drowsiness
- swelling around your face or swollen glands in your neck, armpit or groin
- unusual bleeding or bruising
- a sore throat or more infections than usual
- rare skin condition, with severe blisters, and bleeding from the lips, eyes, mouth, nose and genital area (Stevens-Johnson syndrome)
- severe skin reaction, starting with a painful red area, developing into large blisters then peeling of layers of skin (toxic epidermal necrolysis)

In many cases these symptoms will be signs of less serious side effects. However, you must be aware

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

that they are potentially serious – so, if you notice any of these symptoms see a doctor as soon as possible.

Call your doctor at once if you have any of these serious side effects:

- seizures that happen more often
- trouble in breathing, swelling of face, mouth, hands or feet
- depression
- hallucinations (“seeing” or “hearing” things that aren’t really there)

Other side effects include:

- changes which may show up in blood tests
  - including reduced numbers of red blood cells (anaemia), reduced number of white blood cells, reduced numbers of platelets which can cause bleeding or bruising.
- headache
- changes in liver function
- feeling dizzy or drowsy
- clumsiness and lack of co-ordination
- feeling “wobbly” or unsteady when you move about
- rapid, uncontrollable eye movements
- anxiety
- confusion
- irritability
- difficulty in sleeping
- shaking or tremors
- double or blurred vision
- feeling tired
- nausea (feeling sick) or vomiting (being sick)
- sensitivity of the skin to light

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

- aggression
- pain in your back or joints, or elsewhere
- numbness, tingling, pins and needles
- sensation of spinning or whirling (vertigo)
- worsening of Parkinson's disease

If any of the side effects become severe or troublesome, please tell your doctor or pharmacist.

Not all side effects reported for **GIROTEC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **GIROTEC**, please consult your doctor, pharmacist or other healthcare professional for advice.

## 6. STORING AND DISPOSING OF GIROTEC

Store at or below 30 °C (room temperature). Keep blisters in the original carton until required for use.

Keep the containers tightly closed.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 7. PRESENTATION OF GIROTEC

### GIROTEC 25 mg TABLETS:

- Blister Pack:

Tablets are packed in clear PVC laminated with a clear and printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

- HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

Each container contains 60 tablets.

Pack size: 60's - One HDPE container contains 60 tablets.

#### **GIROTEC50 mg TABLETS:**

1) Blister Pack:

Tablets are packed in clear PVC laminated with a clear and printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

2) HDPE Container Pack:

Tablets are packed in 40 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

Each container contains 60 tablets.

Pack size: 60's - One HDPE container contains 60 tablets.

#### **GIROTEC 100 mg TABLETS:**

- Blister Pack:

Tablets are packed in clear PVC laminated with a clear and printed aluminium foil. Each blister contains 10 tablets.

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

- HDPE Container Pack:

Tablets are packed in 60 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

Each container contains 60 tablets.

Pack size: 60's - One HDPE container contains 60 tablets.

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

#### **GIROTEC 200 mg TABLETS:**

- Blister Pack:

Tablets are packed in clear PVC laminated with a clear and printed aluminium foil.

Each blister contains 10 tablets.

Pack size: 60's – Each carton contains 6 blisters of 10 tablets each.

- HDPE Container Pack:

Tablets are packed in 120 ml white opaque HDPE containers with white opaque polypropylene closures with induction sealing wad, containing cotton coil.

Each container contains 60 tablets.

Pack size: 60's - One HDPE container contains 60 tablets.

#### **8. IDENTIFICATION OF GIROTEC**

**GIROTEC 25 mg:** White to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '80' on flat side.

**GIROTEC 50 mg:** White to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '79' on flat side.

**GIROTEC 100 mg:** White to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '78' on flat side.

**GIROTEC 200 mg:** White to off-white, rounded square shaped uncoated tablets debossed with 'H' on multifaceted side and '77' on flat side.

#### **9. REGISTRATION NUMBER/REFERENCE NUMBER**

**GIROTEC 25 mg TABLETS:** 43/2.5/0047

**GIROTEC 50 mg TABLETS:** 43/2.5/0048

**GIROTEC 100 mg TABLETS:** 43/2.5/0049

**GIROTEC 200 mg TABLETS:** 43/2.5/0050

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Aurobindo Pharma (Pty) Ltd

Woodhill Office Park, Building 1, 53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

**11. DATE OF PUBLICATION**

26 November 2015

**12. DATE OF REVISION**

09 March 2022

**Applicant/PHCR** : AUROBINDO PHARMA (PTY) LTD  
**Proprietary name** : GIROTEC 25 mg / 50 mg / 100 mg / 200 mg TABLETS  
**Dosage form and strength** : TABLET 25 mg / 50 mg / 100 mg / 200 mg  
**Final approved PIL** : 09 March 2022

---

--