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**APPROVED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S5

**LENIO 20 mg** (Tablet)

**LENIO 30 mg** (Tablet)

Paroxetine hydrochloride hemihydrate

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

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

The active substance is paroxetine.

**LENIO 20 mg:**

Each film-coated tablet contains paroxetine hydrochloride hemihydrate equivalent to 20 mg paroxetine.

**LENIO 30 mg:**

Each film-coated tablet contains paroxetine hydrochloride hemihydrate equivalent to 30 mg paroxetine.

The other ingredients contained in **LENIO** are calcium hydrogen phosphate anhydrous, calcium hydrogen phosphate dihydrate, lactose monohydrate, magnesium stearate and sodium starch glycolate.

The coating material for **LENIO 20 mg** contains hypromellose, polyethylene glycol 400, polysorbate 80 and titanium dioxide (C.I. No: 77891).

The coating material for **LENIO 30 mg** contains FD&C blue # 2/indigo carmine aluminium lake (C.I. No: 73015), hypromellose, polyethylene glycol 400, polysorbate 80 and titanium dioxide (C.I. No: 77891)

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## **2. WHAT LENIO IS USED FOR**

**LENIO** belongs to a class of medications called selective serotonin reuptake inhibitors (SSRIs). It works by increasing the amount of serotonin, a natural substance in the brain that helps maintain mental balance.

**LENIO** is used to treat:

- Depression
- Obsessive compulsive disorder (bothersome thoughts that won't go away and the need to perform certain actions over and over)
- Social phobia (extreme fear of interacting with others or performing in front of others that interferes with normal life)
- Panic disorder (sudden, unexpected attacks of extreme fear and worry about these attacks).

## **3. BEFORE YOU TAKE LENIO**

**Do not take LENIO:**

- If you have ever had an allergic reaction to paroxetine or any of the other ingredients found in **LENIO**.
- If you are taking medicines called monoamine oxidase inhibitors (MAOIs). You must wait at least 2 weeks after stopping a MAO inhibitor before you can take **LENIO**. After you stop taking **LENIO**, you must wait at least 2 weeks before you start taking a MAO inhibitor.
- If you are under the age of 18 years.
- If you are taking a medicine called thioridazine.

**Take special care with LENIO:**

- **LENIO** should not be used for children and adolescents under 18 years because it has not been proven to be an effective and safe medicine for this age group.
- You should know that your mental health may change in unexpected ways when you take **LENIO** or other antidepressants. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms, especially if they are new

and severe: new or worsening depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep; aggressive behaviour; irritability, hostility; acting without thinking; severe restlessness; and mania (mental and/or physical hyperactivity).

- When stopping **LENIO**, your doctor will gradually reduce your dose to help reduce the chance of withdrawal effects.
- A low level of sodium in the blood may occur, which is usually reversible when **LENIO** is stopped. This occurs mainly in the elderly.
- If you are taking a medicine called risperidone (see **Taking other medicines with LENIO**).
- If you are taking neuroleptic or antipsychotic medicines (see **Taking other medicines with LENIO**).
- If you develop seizures while taking **LENIO**, **LENIO** should be discontinued.
- Tell your doctor:
  - If you have or have ever had episodes of mania (overactive behaviour or thoughts).
  - If you have a history of bleeding disorders or are taking medicines that may increase your risk of bleeding.
  - If you have heart disease.
  - If you have liver or kidney disease.
  - If you have seizures or epilepsy.
  - If you are having electroconvulsive therapy (ECT).
  - If you have glaucoma (raised pressure in the eye).

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

- Take your tablets with food.
- Do not drink alcohol while you are taking **LENIO**. Alcohol may make your symptoms or side-effects worse.

#### **Pregnancy and Breast-feeding:**

- Tell your doctor if you are pregnant or plan to become pregnant, or are breast-feeding.

- The safety of **LENIO** in pregnancy and breast-feeding has not been confirmed.

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

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

You should know that **LENIO** may make you drowsy and affect your judgement and thinking. Do not drive a car or operate machinery until you know how this medication affects you.

#### **Taking other medicines with LENIO:**

Some medicines may interact with paroxetine. Before taking **LENIO**, tell your doctor if you are using any of the following medicines:

- Cimetidine, used to treat ulcers.
- Phenytoin, and other anti-convulsant medicines, used to treat fits or epilepsy.
- Debrisoquine
- Sparteine
- Medicines called monoamine oxidase inhibitors (MAOIs) such as moclobemide.
- Other antidepressants including tryptophan and tricyclic antidepressants such as nortriptyline, amitriptyline, imipramine and desipramine.
- A neuroleptic/anti-psychotic medicine called thioridazine – Do not take **LENIO** if you are taking thioridazine.
- Medicines such as lithium, risperidone, perphenazine (called anti-psychotics) used to treat some psychiatric conditions.
- Procyclidine, used to relieve tremor, especially in Parkinson's disease.
- Propafenone and medicines used to treat an irregular heartbeat.
- Metoprolol, a beta-blocker used to treat high blood pressure and heart problems.
- Warfarin or other medicines (called anticoagulants) used to thin the blood.

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **LENIO** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

#### **4. HOW TO TAKE LENIO**

Always take **LENIO** 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 **LENIO** is too strong or too weak, talk to your doctor or pharmacist.

- Take this medication only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor.
- Take your tablets in the morning with food.
- Swallow them with a drink of water.
- Do not chew.
- Your doctor will advise you what dose to take when you first start taking **LENIO**. If you don't start to feel better, your doctor may decide to increase the dose gradually, 10 mg at a time, up to a maximum daily dose.
- The usual doses for the different conditions are:
  - Depression:  
The starting dose is 20 mg daily. If required, your doctor can gradually increase your dose to a maximum of 50 mg daily.
  - Panic disorder (panic attacks):  
The starting dose is 10 mg daily. The recommended daily dose is 40 mg. The maximum daily dose is 60 mg.
  - Obsessive Compulsive Disorder (obsessions and compulsions):  
The starting dose is 20 mg daily. The recommended daily dose is 40 mg. The maximum daily dose is 60 mg.
  - Social phobia (fear or avoidance of social situations):

The recommended dose is 20 mg daily. If required, your doctor can gradually increase your dose to a maximum of 60 mg daily.

Your doctor will advise you on the daily dose you should take.

- Children - **LENIO** should not be used for children under 18 years. In children, hostility, suicidal thoughts and harming themselves may occur with **LENIO**.
- Older people – The maximum dose for elderly patients is 40 mg per day.
- Patients with liver or kidney disease – If you have liver or kidney disease, your doctor may decide that you should have a lower dose of **LENIO** than usual.
- You doctor will tell you how long you need to keep taking your tablets. This may be for many months or even longer.
- Do not stop taking **LENIO** without talking to your doctor (see **Take special care with LENIO**).

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

- Seek emergency medical attention if you think you have used too much of this medicine.
- Symptoms of overdose may include: vomiting, widened pupils, fever, changes in blood pressure, headache, sudden muscle twitching or jerking that you cannot control, feeling agitated, feeling anxious, increased rate of heart beat and coma.

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

**If you forget to take LENIO:**

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

**Effects when treatment with LENIO is stopped:**

You may have the following withdrawal symptoms after you stop taking **LENIO**:

- feeling agitated; feelings like pins and needles; electric shock sensations; sleep disturbances; inability to sleep; feeling anxious; confusion; feeling sick (nausea); sweating; headache; diarrhoea;

tremor (shakiness); feeling nervous; feeling dizzy, unsteady or off-balance. Do not stop taking this medicine suddenly without first speaking to your doctor.

Tell your doctor about any concerns you have while stopping **LENIO**.

## **5. POSSIBLE SIDE-EFFECTS**

**LENIO** can have side-effects.

Get emergency medical help at once if you have any of these signs of an allergic reaction:

- hives (red and lumpy skin rash)
- difficulty breathing
- swelling of your face, lips, tongue, or throat.

Call your doctor immediately if you have any of these serious side-effects:

- Seizure (convulsions).
- Abnormal bruising or bleeding.
- Mania (mental and/or physical hyperactivity).
- If you feel restless and feel like you can't sit or stand still.
- Muscle stiffness or twitching, uncontrollable shaking of a part of the body.
- If you feel tired, weak or confused and have achy, stiff or uncoordinated muscles this may be because your blood is low in sodium.
- If you have some or all of the following symptoms you may have something called serotonin syndrome: feeling confused, feeling agitated, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat.
- Acute glaucoma: If your eyes become painful and you develop blurred vision.

Other possible side-effects are:

- fluid or water retention; sleepiness; inability to sleep; confusion; having hallucinations (strange visions or sounds); decreased appetite; dizziness; feeling weak; swelling of hands and feet due to retained fluid; blurred vision; yawning; an inability to urinate (urinary retention); change in sex drive or sexual function; abnormal production of breast milk; nausea (feeling sick); constipation; diarrhoea; dry mouth; sweating; sensitivity to sunlight; skin rashes; effects on the liver showing up

in blood tests of your liver function; liver problems that make the skin or whites of the eyes go yellow.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **LENIO**.

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

## **6. STORING AND DISPOSING OF LENIO**

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

Store at or below 25 °C (room temperature). Protect from light and moisture. Do not remove from the outer carton until required for use.

Return all unused medicine to your pharmacist.

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

## **7. PRESENTATION OF LENIO**

### **LENIO 20 mg:**

Tablets are packed in 250 micron white opaque PVC film laminated with 25 micron PE coated with 90 gsm PVdC and 25 micron printed Aluminium foil. Each blister contains 10 tablets.

Pack size: 30's: 3 blisters of 10 tablets each.

### **LENIO 30 mg:**

Tablets are packed in 250 micron white opaque PVC film laminated with 25 micron PE coated with 90 gsm PVdC and 25 micron printed Aluminium foil. Each blister contains 10 tablets.

Pack size: 30's: 3 blisters of 10 tablets each.

## **8. IDENTIFICATION OF LENIO**

### **LENIO 20 mg:**

White to off-white coloured film-coated modified capsule shaped, biconvex tablets debossed with '56' on one side and 'C' with a deep breakline on the other side.

**LENIO 30 mg:**

Blue coloured film-coated modified capsule shaped, biconvex tablets debossed with 'F' on one side and '12' on the other side.

**9. REGISTRATION NUMBERS/REFERENCE NUMBERS**

**LENIO 20 mg:** 42/1.2/0208

**LENIO 30 mg:** 42/1.2/0209

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

Aurogen South Africa (Pty) Ltd

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**11. DATE OF PUBLICATION**

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