

## Medication Guide

### PAROXETINE (pa rox' e teen) EXTENDED-RELEASE TABLETS, USP

Paroxetine extended-release tablets, 12.5 mg contain FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

#### **What is the most important information I should know about paroxetine extended-release tablets?**

##### **Paroxetine extended-release tablets can cause serious side effects, including:**

- **Increased risk of suicidal thoughts or actions.** Antidepressant medicines may increase suicidal thoughts and actions in some children and young adults within the first few months of treatment or when the dose is changed. Paroxetine extended-release tablets is not for use in people younger than 18 years of age.

##### **How can I watch for and try to prevent suicidal thoughts and actions?**

- Depression or other serious mental illnesses are the most important causes of suicidal thoughts and actions.
- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts or feelings or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts or feelings or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

##### **Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms, especially if they are new, worse, or worry you:**

- attempts to commit suicide
- acting aggressive or violent
- new or worse depression
- feeling agitated, restless, angry, or irritable
- an increase in activity and talking more than what is normal for you
- acting on dangerous impulses
- thoughts about suicide or dying
- new or worse anxiety or panic attacks
- trouble sleeping
- other unusual changes in behavior or mood

#### **What is Paroxetine Extended-Release Tablets?**

Paroxetine extended-release tablets is a prescription medicine used in adults to treat:

- A certain type of depression called Major Depressive Disorder (MDD)
- Panic Disorder
- Social Anxiety Disorder (SAD)
- Premenstrual Dysphoric Disorder (PMDD)

#### **Do not take paroxetine extended-release tablets if you:**

- take a monoamine oxidase inhibitor (MAOI)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or intravenous methylene blue
- are taking thioridazine

- are taking pimozide
- are allergic to paroxetine or any of the ingredients in paroxetine extended-release tablets. See the end of this Medication Guide for a complete list of ingredients in paroxetine extended-release tablets.

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI or one of these medicines, including intravenous methylene blue.

**Do not start taking an MAOI for at least 14 days after you stop treatment with paroxetine extended-release tablets.**

**Before taking paroxetine extended-release tablets, tell your healthcare provider about all your medical conditions, including if you:**

- have heart problems
- have or had bleeding problems
- have, or have a family history of bipolar disorder, mania or hypomania
- have or had seizures or convulsions
- have glaucoma (high pressure in the eye)
- have low sodium levels in your blood
- have bone problems
- have kidney or liver problems
- are pregnant or plan to become pregnant. Paroxetine may harm your unborn baby. Talk to your healthcare provider about the risks to your unborn baby if you take paroxetine extended-release tablets during pregnancy. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with paroxetine extended-release tablets.
- are breastfeeding or plan to breastfeed. Paroxetine passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with paroxetine extended-release tablets.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Paroxetine extended-release tablets and some other medicines may affect each other causing possible serious side effects. Paroxetine extended-release tablets may affect the way other medicines work and other medicines may affect the way paroxetine extended-release tablets works.

**Especially tell your healthcare provider if you take:**

- medicines used to treat migraine headaches called triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- amphetamines
- St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), or warfarin
- diuretics
- tamoxifen

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your

healthcare provider can tell you if it is safe to take paroxetine extended-release tablets with your other medicines.

Do not start or stop any other medicines during treatment with paroxetine extended-release tablets without talking to your healthcare provider first. Stopping paroxetine extended-release tablets suddenly may cause you to have serious side effects. See, **“What are the possible side effects of paroxetine extended-release tablets?”**

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

#### **How should I take paroxetine extended-release tablets?**

- Take paroxetine extended-release tablets exactly as your healthcare provider tell you to. Your healthcare provider may need to change the dose of paroxetine extended-release tablets until it is the right dose for you.
- Take paroxetine extended-release tablets one time each day in the morning.
- Paroxetine extended-release tablets may be taken with or without food.
- Swallow paroxetine extended-release tablets whole. **Do not** chew or crush paroxetine extended-release tablets.
- If you take too much paroxetine extended-release tablets, call your poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

#### **What are possible side effects of paroxetine extended-release tablets?**

##### **Paroxetine extended-release tablets can cause serious side effects, including:**

- See, **“What is the most important information I should know about paroxetine extended-release tablets?”**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take paroxetine extended-release tablets with certain other medicines. See, **“Who should not take paroxetine extended-release tablets?”** **Call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:
  - agitation
  - seeing or hearing things that are not real (hallucinations)
  - confusion
  - coma
  - fast heart beat
  - changes in blood pressure
  - dizziness
  - sweating
  - flushing
  - high body temperature (hyperthermia)
  - shaking (tremors), stiff muscles, or muscle twitching
  - loss of coordination
  - seizures
  - nausea, vomiting, diarrhea
- **Medicine interactions.** Taking paroxetine extended-release tablets with certain other medicines including thioridazine and pimozide may increase the risk of developing a serious heart problem called QT prolongation.

- **Abnormal bleeding.** Taking paroxetine extended-release tablets with aspirin, NSAIDs, or blood thinners may add to this risk. Tell your healthcare provider about any unusual bleeding or bruising.
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take paroxetine extended-release tablets. Symptoms may include:
  - greatly increased energy
  - racing thoughts
  - unusually grand ideas
  - talking more or faster than usual
  - severe problems sleeping
  - reckless behavior
  - excessive happiness or irritability
- **Discontinuation syndrome.** Suddenly stopping paroxetine extended-release tablets may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
  - nausea
  - sweating
  - changes in your mood
  - irritability and agitation
  - dizziness
  - electric shock feeling (paresthesia)
  - tremor
  - anxiety
  - confusion
  - headache
  - tiredness
  - problems sleeping
  - ringing in your ears (tinnitus)
  - seizures
- **Seizures (convulsions).**

**Eye problems (angle-closure glaucoma).** Paroxetine extended-release tablets may cause a type of eye problem called angle-closure glaucoma in people with certain other eye conditions. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.
- **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood that may be serious and may cause death, can happen during treatment with paroxetine extended-release tablets. Elderly people and people who take certain medicines may be at a greater risk for developing low sodium levels in your blood. Signs and symptoms may include:
  - headache
  - difficulty concentrating
  - memory changes
  - confusion
  - weakness and unsteadiness on your feet which can lead to falls

**In more severe or more sudden cases, signs and symptoms include:**

- seeing or hearing things that are not real (hallucinations)
- fainting
- seizures
- coma
- stopping breathing (respiratory arrest)

- **Bone fractures.**

**The most common side effects paroxetine extended-release tablets include:**

- male and female sexual function problems
- blurred vision
- weakness (asthenia)
- constipation
- decreased appetite
- diarrhea
- dry mouth
- problems sleeping
- nausea
- sleepiness
- sweating
- tremor
- dizziness

These are not all the possible side effects of paroxetine extended-release tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store paroxetine extended-release tablets?**

Store paroxetine extended-release tablets at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep paroxetine extended-release tablets and all medicines out of the reach of children.**

**General information about the safe and effective use of paroxetine extended-release tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take paroxetine extended-release tablets for a condition for which it was not prescribed. Do not give paroxetine extended-release tablets to other people, even if they have the same symptoms that you have. It may harm them. You may ask your healthcare provider or pharmacist for information about paroxetine extended-release tablets that is written for healthcare professionals.

**What are the ingredients in paroxetine extended-release tablets?**

**Active ingredient:** paroxetine hydrochloride hemihydrate USP

**Inactive ingredients:** aluminum oxide, colloidal silicon dioxide, hydrogenated vegetable oil, hypromelloses, iron oxide black, lactose monohydrate, magnesium stearate, methacrylic acid co-polymer dispersion, microcrystalline cellulose, polyethylene glycols, povidone, propylene glycol, shellac glaze, talc, titanium dioxide, triacetin and triethyl citrate.

The 12.5 mg tablets also contain D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 5

Aluminum Lake (tartrazine) and FD&C Yellow No. 6 Aluminum Lake.  
The 25 mg tablets also contain D&C Red No. 30 Aluminum Lake and FD&C Blue No. 2 Aluminum Lake.

The 37.5 mg tablets also contain FD&C Blue No. 1 Aluminum Lake.

Manufactured for:

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United States.

Manufactured by:

**Lupin Limited**

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For more information about paroxetine extended-release tablets go to [www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com) or call Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

This Medication Guide has been approved by the U.S. Food and Drug Administration.