

Paroxetine (pa rox' e teen) Extended-Release Tablets

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 are not for use in people younger than 18 years of age.

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

- o Depression or other serious mental illnesses are the most important causes of suicidal thoughts and actions.
- o 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.
- o 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.
- o 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:

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

What are paroxetine extended-release tablets?

Paroxetine extended-release tablets are 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 extended-release tablets may harm your unborn baby.
 - Taking paroxetine extended-release tablets during your first trimester of pregnancy may cause your baby to be at an increased risk of having a heart problem (cardiac malformations) at birth.
 - Taking paroxetine extended-release tablets during your third trimester of pregnancy may cause your baby to have breathing, temperature, and feeding problems, low muscle tone (floppy baby syndrome), and irritability after birth and may cause your baby to be at an increased risk of a serious lung problem at birth. Talk to your healthcare provider about the risk 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.
 - There is a pregnancy registry for females who are exposed to paroxetine extended-release tablets during pregnancy. The purpose of the registry is to collect information about the health of females exposed to paroxetine extended-release tablets and their baby. If you become pregnant during treatment with paroxetine extended-release tablets talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>.
- 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
- lithium
- tramadol, fentanyl, meperidine, methadone, or other opioids
- 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 1 time each day in the morning.
- Take paroxetine extended-release tablets 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:
 - o agitation
 - o seeing or hearing things that are not real (hallucinations)
 - o confusion
 - o coma
 - o fast heart beat
 - o changes in blood pressure
 - o dizziness
 - o sweating
 - o flushing
 - o high body temperature (hyperthermia)
 - o shaking (tremors), stiff muscles, or muscle twitching
 - o loss of coordination
 - o seizures
 - o 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:
 - o greatly increased energy
 - o racing thoughts
 - o unusually grand ideas
 - o talking more or faster than usual
 - o severe problems sleeping
 - o reckless behavior
 - o 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:
 - o nausea
 - o sweating
 - o changes in your mood
 - o irritability and agitation
 - o dizziness
 - o electric shock feeling (paresthesia)
 - o tremor
 - o anxiety
 - o confusion
 - o headache
 - o tiredness
 - o problems sleeping
 - o ringing in your ears (tinnitus)
 - o 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:
 - o headache
 - o difficulty concentrating
 - o memory changes
 - o confusion
 - o weakness and unsteadiness on your feet which can lead to falls

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

 - o seeing or hearing things that are not real (hallucinations)
 - o fainting
 - o seizures
 - o coma
 - o stopping breathing (respiratory arrest)
- **Bone fractures.**
- **Sexual problems (dysfunction).** Taking selective serotonin reuptake inhibitors (SSRIs), including paroxetine extended-release tablets, may cause sexual problems.

Symptoms in males may include:

 - o Delayed ejaculation or inability to have an ejaculation
 - o Decreased sex drive
 - o Problems getting or keeping an erection

Symptoms in females may include:

 - o Decreased sex drive
 - o Delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with paroxetine extended-release tablets. There may be treatments your healthcare provider can suggest.

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

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

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).
- 30's bottle comes in a child-resistant package.

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

Inactive ingredients: colloidal silicon dioxide, glyceryl dibehenate, hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid copolymer, povidone K-30, talc and triethyl citrate.

The film-coating material contains hypromellose, polyethylene glycol 400, polyethylene glycol 6000 and titanium dioxide. Additionally, 25 mg tablets contain D&C Red No. 30 Lake and polysorbate 80 and 37.5 mg tablets contain FD&C Blue No. 2 Aluminium Lake and talc.

Medication Guide available at <https://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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For more information about paroxetine extended-release tablets call Alembic Pharmaceuticals Limited at 1-866-210-9797.

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

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