

Medication Guide

Paroxetine Extended-Release Tablets, USP

(pa rox' e teen)

Read the Medication Guide that comes with paroxetine extended-release tablets before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

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

Paroxetine extended-release tablets and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **Paroxetine extended-release tablets and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, and young adults within the **first few months of treatment or when the dose is changed**.
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts and actions.
- Watch for these changes, and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when paroxetine extended-release tablets are started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

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

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. Paroxetine extended-release tablets may be associated with these serious side effects:

2. Serotonin Syndrome or Neuroleptic Malignant Syndrome-like reactions.

This condition can be life-threatening and may include:

- agitation, hallucinations, coma, or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity

3. Visual problems

- eye pain
- changes in vision
- swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

4. Severe allergic reactions:

- trouble breathing
- swelling of the face, tongue, eyes, or mouth
- rash, itchy welts (hives), or blisters, alone or with fever or joint pain

5. Abnormal bleeding: Paroxetine extended-release tablets and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin[®], Jantoven[®]), a non-steroidal anti-inflammatory

drug (NSAIDs, like ibuprofen or naproxen), or aspirin.

6. Seizures or convulsions

7. Manic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

8. Changes in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

9. Low salt (sodium) levels in the blood. Elderly people may be at greater risk for this. Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking, or memory problems

Do not stop paroxetine extended-release tablets without first talking to your healthcare provider. Stopping paroxetine extended-release tablets too quickly may cause serious symptoms including:

- anxiety, irritability, high or low mood, feeling restless, or changes in sleep habits
- headache, sweating, nausea, dizziness
- electric shock-like sensations, shaking, confusion

What are paroxetine extended-release tablets?

Paroxetine extended-release tablets are a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider. Paroxetine extended-release tablets are also used to treat:

- Major Depressive Disorder (MDD)
- Panic Disorder
- Social Anxiety Disorder
- Premenstrual Dysphoric Disorder (PMDD)

Talk to your healthcare provider if you do not think that your condition is getting better with treatment using paroxetine extended-release tablets.

Who should not take paroxetine extended-release tablets?

Do not take paroxetine extended-release tablets if you:

- 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.
- take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
 - Do not take an MAOI within 2 weeks of stopping paroxetine extended-release tablets unless directed to do so by your physician.
- Do not start paroxetine extended-release tablets if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.
- **People who take paroxetine extended-release tablets close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:**
 - high fever
 - uncontrolled muscle spasms
 - stiff muscles
 - rapid changes in heart rate or blood pressure
 - confusion
 - loss of consciousness (pass out)
- **take MELLARIL[®] (thioridazine). Do not take MELLARIL[®] together with paroxetine extended-release tablets because this can cause serious heart rhythm problems or sudden death.**
- **take the antipsychotic medicine pimozide (ORAP[®]) because this can cause serious heart problems.**

What should I tell my healthcare provider before taking paroxetine extended-release tablets? Ask if you are not sure.

Before starting paroxetine extended-release tablets, tell your healthcare provider if you:

- **are pregnant, may be pregnant, or plan to become pregnant.** There is a possibility that paroxetine extended-release tablets may harm your unborn baby, including an increased risk of birth defects, particularly heart defects.

Other risks may include a serious condition in which there is not enough oxygen in the baby's blood. Your baby may also have certain other symptoms shortly after birth. Premature births have also been reported in some women who used paroxetine extended-release tablets during pregnancy.

- **are breastfeeding.** Paroxetine passes into your milk. Talk to your healthcare provider about the best way to feed your baby while taking paroxetine extended-release tablets.
- are taking certain drugs such as:
 - triptans used to treat migraine headache
 - other antidepressants (SSRIs, SNRIs, tricyclics, or lithium) or antipsychotics
 - drugs that affect serotonin, such as lithium, tramadol, tryptophan, St. John's wort
 - certain drugs used to treat irregular heart beats
 - certain drugs used to treat schizophrenia
 - certain drugs used to treat HIV infection
 - certain drugs that affect the blood, such as warfarin, aspirin, and ibuprofen
 - certain drugs used to treat epilepsy
 - atomoxetine
 - cimetidine
 - fentanyl
 - metoprolol
 - pimozone
 - procyclidine
 - tamoxifen
- have liver problems
- have kidney problems
- have heart problems
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have a history of a stroke
- have high blood pressure
- have or had bleeding problems
- have glaucoma (high pressure in the eye)

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Paroxetine extended-release tablets and some medicines may interact with each other, may not work as well, or may cause serious side effects. Your healthcare provider or pharmacist can tell you if it is safe to take paroxetine extended-release tablets with your other medicines. Do not start or stop any medicine while taking paroxetine extended-release tablets without talking to your healthcare provider first.

If you take paroxetine extended-release tablets, you should not take any other medicines that contain paroxetine, including paroxetine tablets and PEVEA® (paroxetine mesylate).

How should I take paroxetine extended-release tablets?

- Take paroxetine extended-release tablets exactly as prescribed. Your healthcare provider may need to change the dose of paroxetine extended-release tablets until it is the right dose for you.
- Paroxetine extended-release tablets may be taken with or without food.
- Paroxetine extended-release tablets should not be chewed or crushed and should be swallowed whole.
- If you miss a dose of paroxetine extended-release tablets, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of paroxetine extended-release tablets at the same time.
- If you take too much paroxetine, call your healthcare provider or poison control center right away, or get emergency treatment.
- Do not stop taking paroxetine extended-release tablets suddenly without talking to your doctor (unless you have symptoms of a severe allergic reaction). If you need to stop taking paroxetine extended-release tablets, your healthcare provider can tell you how to safely stop taking it.

What should I avoid while taking paroxetine extended-release tablets?

Paroxetine extended-release tablets can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how paroxetine extended-release tablets affect you. Do not drink alcohol while using paroxetine extended-release tablets.

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

Paroxetine extended-release tablets may cause serious side effects, including all of those described in the section entitled "What is the most important information I should know about paroxetine extended-release tablets?"

Common possible side effects in people who take paroxetine extended-release tablets include:

- nausea
- sleepiness
- feeling anxious or trouble sleeping
- sexual problems
- sweating
- shaking
- constipation
- yawning
- blurred vision
- diarrhea
- dry mouth
- decreased appetite
- weakness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of paroxetine extended-release tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or 1-800-332-1088.

How should I store paroxetine extended-release tablets?

- Store paroxetine extended-release tablets at 20° to 25 °C (68° to 77°F).
- Keep paroxetine extended-release tablets away from light.
- Keep bottle of paroxetine extended-release tablets closed tightly.

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

General information about paroxetine extended-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use 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 condition. It may harm them.

This Medication Guide summarizes the most important information about paroxetine extended-release tablets. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about paroxetine extended-release tablets that is written for healthcare professionals.

For more information about paroxetine extended-release tablets, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

What are the ingredients in paroxetine extended-release tablets, USP?

Active ingredient: paroxetine hydrochloride

Inactive ingredients in tablets: colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid copolymer type C, microcrystalline cellulose, polydextrose, polyethylene glycol, polysorbate 80, sodium hydroxide, talc, titanium dioxide, triacetin and triethyl citrate. In addition, the 25 mg tablets also contain the following coloring agents: D&C Red No. 30 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake and the 37.5 mg tablets also contain D&C Red No. 30 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, lecithin and sodium alginate.

In addition, paroxetine extended-release tablets may also contain imprinting ink consisting of either black pigment and natural resin or black iron oxide and propylene glycol.

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