

MEDICATION GUIDE
Paroxetine Tablets, USP
(pa rox' e teen)

Read the Medication Guide that comes with paroxetine 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?

Paroxetine and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **Paroxetine and other antidepressant medicines may increase suicidal thoughts or actions** in some children, teenagers, or 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 or 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 is 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 or 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 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 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 without first talking to your healthcare provider. Stopping paroxetine 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 is paroxetine?

Paroxetine is 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 is also used to treat:

- Major Depressive Disorder (MDD)
- Obsessive Compulsive Disorder (OCD)
- Panic Disorder
- Social Anxiety Disorder
- Generalized Anxiety Disorder (GAD)
- Posttraumatic Stress Disorder (PTSD)

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

Who should not take paroxetine?

Do not take paroxetine if you:

- are allergic to paroxetine or any of the ingredients in paroxetine tablets. See the end of this Medication Guide for a complete list of ingredients in paroxetine 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 unless directed to do so by your physician.
 - Do not start paroxetine if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.
- **People who take paroxetine 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 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? Ask if you are not sure.

Before starting paroxetine, tell your healthcare provider if you:

- **are pregnant, may be pregnant, or plan to become pregnant.** There is a possibility that paroxetine 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 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.
- 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 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 with your other medicines. Do not start or stop any medicine while taking paroxetine without talking to your healthcare provider first.

If you take paroxetine, you should not take any other medicines that contain paroxetine hydrochloride, including PAXIL CR and PEXEVA® (paroxetine mesylate).

How should I take paroxetine?

- Take paroxetine exactly as prescribed. Your healthcare provider may need to change the dose of paroxetine until it is the right dose for you.
- Paroxetine may be taken with or without food.
- If you are taking paroxetine oral suspension, shake the suspension well before use.
- If you miss a dose of paroxetine, 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 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 suddenly without talking to your doctor (unless you have symptoms of a severe allergic reaction). If you need to stop taking paroxetine, your healthcare provider can tell you how to safely stop taking it.

What should I avoid while taking paroxetine?

Paroxetine 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 affects you. Do not drink alcohol while using paroxetine.

What are possible side effects of paroxetine?

Paroxetine 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?"

Common possible side effects in people who take paroxetine include:

- nausea
- sleepiness
- weakness
- dizziness
- feeling anxious or trouble sleeping
- sexual problems
- sweating
- shaking
- not feeling hungry
- dry mouth
- constipation
- infection
- yawning

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. 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?

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

Keep paroxetine and all medicines out of the reach of children.

General information about paroxetine

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use paroxetine for a condition for which it was not prescribed. Do not give paroxetine to other people, even if they have the same condition. It may harm them.

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

For more information about paroxetine call Apotex Drug Information at 1-800-706-5575.

What are the ingredients in paroxetine tablets?

Active ingredient: paroxetine hydrochloride

Inactive ingredients: anhydrous lactose, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, sodium starch glycolate and titanium dioxide.

PAXIL and PAXIL CR are registered trademarks of GlaxoSmithKline. The other brands listed are trademarks of their respective owners. This Medication Guide has been approved by the U.S. Food and Drug Administration.

**APOTEX INC.
PAROXETINE TABLETS, USP
10 mg, 20 mg, 30 mg and 40 mg**

Manufactured by
Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

Manufactured for
Apotex Corp.
Weston, FL
33326

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