

HOW SUPPLIED

PAXIL CR is supplied as an enteric film-coated, controlled-release, round tablet, as follows:

12.5-mg yellow tablets

NDC 60505-3668-3 Bottles of 30 (engraved with GSK and 12.5)

25-mg pink tablets

NDC 60505-3669-3 Bottles of 30 (engraved with GSK and 25)

37.5 mg blue tablets

NDC 60505-3670-3 Bottles of 30 (engraved with GSK and 37.5)

Store at or below 25°C (77°F) [see USP].

PAXIL CR is a registered trademark of GlaxoSmithKline.

Manufactured by

GlaxoSmithKline

Research Triangle Park, NC 27709

Manufactured for:

Apotex Corp.

Weston, FL 33326

June 2014

PCR-AP:7PI

Medication Guide

PAXIL CR[®] (PAX-il) (paroxetine hydrochloride)

Controlled-Release Tablets

Read the Medication Guide that comes with PAXIL CR 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 PAXIL CR?

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

1. Suicidal thoughts or actions:

- **PAXIL CR 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 PAXIL CR 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 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. PAXIL CR 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:** PAXIL CR 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 PAXIL CR without first talking to your healthcare provider. Stopping PAXIL CR 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 PAXIL CR?

PAXIL CR 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. PAXIL CR is 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 PAXIL CR.

Who should not take PAXIL CR?

Do not take PAXIL CR if you:

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

Before starting PAXIL CR, tell your healthcare provider if you:

- **are pregnant, may be pregnant, or plan to become pregnant.** There is a possibility that PAXIL CR 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 PAXIL CR during pregnancy.
- **are breastfeeding.** PAXIL CR passes into your milk. Talk to your healthcare provider about the best way to feed your baby while taking PAXIL CR.
- 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. PAXIL CR 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 PAXIL CR with your other medicines. Do not start or stop any medicine while taking PAXIL CR without talking to your healthcare provider first.

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

How should I take PAXIL CR?

- Take PAXIL CR exactly as prescribed. Your healthcare provider may need to change the dose of PAXIL CR until it is the right dose for you.
- PAXIL CR may be taken with or without food.
- PAXIL CR controlled-release tablets should not be chewed or crushed and should be swallowed whole.
- If you miss a dose of PAXIL CR, 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 PAXIL CR at the same time.

- If you take too much PAXIL CR, call your healthcare provider or poison control center right away, or get emergency treatment.
- Do not stop taking PAXIL CR suddenly without talking to your doctor (unless you have symptoms of a severe allergic reaction). If you need to stop taking PAXIL CR, your healthcare provider can tell you how to safely stop taking it.

What should I avoid while taking PAXIL CR?

PAXIL CR 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 PAXIL CR affects you. Do not drink alcohol while using PAXIL CR.

What are possible side effects of PAXIL CR?

PAXIL CR may cause serious side effects, including all of those described in the section entitled “What is the most important information I should know about PAXIL CR?”

Common possible side effects in people who take PAXIL CR 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 PAXIL CR. 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 PAXIL CR?

- Store PAXIL CR at or below room temperature (77°F or 25°C).

- Keep PAXIL CR away from light.
- Keep bottle of PAXIL CR closed tightly.

Keep PAXIL CR and all medicines out of the reach of children.

General information about PAXIL CR

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

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

For more information about PAXIL CR call 1-800-706-5575.

What are the ingredients in PAXIL CR?

Active ingredient: paroxetine hydrochloride

Inactive ingredients in tablets: hypromellose, polyvinylpyrrolidone, lactose monohydrate, magnesium stearate, silicon dioxide, glyceryl behenate, methacrylic acid copolymer type C, sodium lauryl sulfate, polysorbate 80, talc, triethyl citrate, titanium dioxide, polyethylene glycols, and 1 or more of the following colorants: Yellow ferric oxide, red ferric oxide, D&C Red No. 30 aluminum lake, FD&C Yellow No. 6 aluminum lake, D&C Yellow No. 10 aluminum lake, FD&C Blue No. 2 aluminum lake.

PAXIL and PAXIL CR are registered trademarks of GlaxoSmithKline.

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

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