



# Paxil/Paxil-CR (paroxetine)

Generic name: Paroxetine

Available strengths: 10 mg, 20 mg, 30 mg, 40 mg tablets;  
10 mg/5 mL oral suspension; 12.5 mg, 25 mg,  
37.5 mg controlled-release tablets (Paxil-CR)

Available in generic: Yes, except oral suspension and  
controlled-release tablets

Drug class: Selective serotonin reuptake inhibitor  
antidepressant

## General Information

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**Paxil (paroxetine)** was approved by the U.S. Food and Drug Administration (FDA) for treatment of major depressive disorder, panic disorder, obsessive-compulsive disorder (OCD), social anxiety disorder, generalized anxiety disorder, and posttraumatic stress disorder. The use of a medication for its approved indications is called its *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* (“off-label”) uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of these medications for these unapproved indications. Paxil may be used to treat other psychiatric disorders, including premenstrual dysphoric disorder and eating disorders such as bulimia nervosa, which is underscored by symptoms of binge eating and vomiting.

Paxil is a **serotonin**-specific medication that works by blocking the reuptake of the neurotransmitter serotonin back into brain cells, thereby increasing its levels in the brain. Depression and other mental disorders may be caused by abnormally low levels of serotonin. This abnormality may in turn produce changes in specific areas of the brain, resulting in psychiatric symptoms such as depression or anxiety. The presumed action of Paxil and other selective serotonin reuptake inhibitors (SSRIs) is to increase serotonin levels, which may help to restore those areas of the brain to normal functioning.

## Dosing Information

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For depression, the usual starting dose of Paxil is 20 mg, taken once a day, usually in the morning. With the controlled-release tablet, Paxil-CR, the starting dose is 25 mg, taken once a day in the morning. If no improvement is seen after 3–4 weeks, the dosage is incrementally increased to a maximum daily dosage of 50 mg for Paxil and 62.5 mg for Paxil-CR. Seniors and people with severe or chronic medical illnesses may

require lower starting dosages. Treatment of other psychiatric disorders such as OCD or panic disorder may require initially lower starting dosages of Paxil or Paxil-CR but require higher ending dosages. For example, in the treatment of panic disorder, the starting dosage is 10 mg/day of Paxil and 12.5 mg/day of Paxil-CR, but the maximum dosage for Paxil and Paxil-CR is 60 mg/day and 75 mg/day, respectively. For patients who cannot take a tablet, Paxil also comes in a liquid form.

Paxil-CR is a controlled-release, and not a sustained-release, formulation. The controlled-release tablet does not provide a longer duration of action over Paxil but offers a smoother rate of absorption with fewer gastrointestinal side effects, such as nausea. The enteric-coated tablets of Paxil-CR should not be chewed, crushed, or cut but swallowed whole, because the tablet structure is what makes the medication controlled-release.

For most people, it may take as long as 3–4 weeks to experience the optimal effects of the medication. The duration of treatment depends on the individual. For most people, the medication may be tapered 6 months after their depression responds to treatment. However, a small percentage of patients will continue to have depressive symptoms after their antidepressant is reduced or stopped. These individuals may benefit from continuing to take Paxil for 1 year or longer.

## Common Side Effects

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The most frequent complaints reported with Paxil are gastrointestinal side effects, including nausea, vomiting, cramping, diarrhea, and heartburn. These side effects may be dramatically reduced by switching to the controlled-release tablet, Paxil-CR. Drowsiness and daytime sedation may be other frequent side effects experienced by individuals taking Paxil. However, a significant number of people taking SSRIs, including Paxil, may experience jitteriness, nervousness, and insomnia, which is common with this class of antidepressants because of its activating properties in the central nervous system.

Paxil is associated with a significant rate of sexual dysfunction in men and women taking the antidepressant. The sexual side effects reported are delayed orgasm in women and retarded ejaculation in men. Some people may experience decreased desire or lack of interest in sexual activity. Occasionally, individuals report headaches, sleepiness, excessive sweating, stomach cramps, diarrhea, and constipation.

People taking Paxil may also experience weight gain. Patients should discuss these side effects with their physician, especially if they continue to be bothersome 3–4 weeks after the medication is started. If a rash or any other severe symptoms develop, patients should contact their physician immediately.

## Adverse Reactions and Precautions

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Paxil may cause drowsiness in some people. Patients should not drive or operate machinery until they are certain that their alertness or coordination is not affected by the medication. Patients with a known allergy to Paxil or who have experienced a severe reaction after taking it should not take Paxil.

## Use in Pregnancy and Breastfeeding: Pregnancy Category C

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Paxil has not been tested in women to determine its safety in pregnancy. The effects of the medication on the developing fetus in pregnant women are unknown. Women who are pregnant or may become pregnant should discuss this with their physician. Some women may experience a recurrence of their depression when they stop their antidepressant. In these circumstances it may be necessary to restart the medication or seek an alternative medication or treatment.

Nursing mothers should not take Paxil because small amounts will pass into breast milk and be ingested by the baby. If stopping the antidepressant is not an alternative, breastfeeding should not be started or should be discontinued.

## Possible Drug Interactions

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The combined use of Paxil with certain medications may result in adverse drug interactions because one medication may alter the blood levels of the other. The clinically significant drug interactions are summarized in the table below.

Coumadin (warfarin)	Paxil may increase the anticoagulant action of Coumadin and increase risk of bleeding; Coumadin therapy should be monitored closely when starting any SSRI.
Tricyclic antidepressants (TCAs)	Paxil may increase the levels of TCAs and the potential for toxicity.
Mellaril (thioridazine)	Paxil may increase the level of Mellaril, an antipsychotic medication, and increase the risk of cardiac arrhythmias.
Phenobarbital	Phenobarbital may decrease the level of Paxil and make it less effective.
Dilantin (phenytoin)	Dilantin may decrease the level of Paxil and make it less effective.
Tagamet (cimetidine)	Tagamet may increase the level of Paxil and the potential for side effects.
Imitrex (sumatriptan)	When Imitrex, a medication for treatment of migraine headaches, was combined with Paxil, some patients reported weakness, jerkiness, and loss of coordination.

Other medications, including herbal supplements (such as St. John's wort), that boost serotonin can result in excessive levels of the neurotransmitter serotonin when combined with Paxil and produce a toxic syndrome known as **serotonin syndrome**. The early signs of serotonin syndrome are restlessness, confusion, tremors, flushing, and involuntary muscle jerks. If the medications are not stopped, the individual may develop more life-threatening complications resulting in muscle disorders, high fever, respiratory problems, clotting problems, and destruction of red blood cells that can lead to acute renal failure. Hence, patients taking Paxil should be alert to the possible signs of serotonin syndrome, which require immediate medical attention and discontinuation of the serotonin-boosting medications.

Antidepressants known as **monoamine oxidase inhibitors (MAOIs)** should not be taken together with Paxil, because the combination may potentially produce a toxic reaction that includes elevated temperature, high blood pressure, and extreme excitation and agitation. Patients should consult their physician or pharmacist before taking any new medications, including over-the-counter medications and herbal supplements, with Paxil.

Patients taking Paxil should avoid alcohol or should consume it in moderation because the combination may worsen depression.

## Overdose

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Like other SSRIs, Paxil is much safer in overdose than the older tricyclic antidepressants and some of the newer antidepressants. There are no reports of fatality following overdose with Paxil alone. However, fatal outcomes have been reported when Paxil was taken in combination with other medications.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency department for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

## Special Considerations

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Most cases of major depression can be treated successfully, usually with medication, psychotherapy, or both. The combination of psychotherapy and antidepressants is very effective in treating moderate to severe depression. The medications improve mood, sleep, energy, and appetite while therapy strengthens coping skills, deals with possible underlying issues, and improves thought patterns and behavior.

In general, antidepressants alone help about 60%–70% of those taking them. Although a few individuals may experience some improvement from antidepressants by the end of the first week, most people do not see significant benefits from their antidepressants until after 3–4 weeks, and it can sometimes take as long as 8 weeks for the medication to produce its full effects. Thus it is critical that patients continue to take their antidepressant long enough for the medication to be beneficial and that patients not get discouraged and stop their medication prematurely if they do not feel better immediately.

The controversial issue of suicide and antidepressants has prompted the FDA to ask manufacturers of some antidepressants, particularly the SSRIs, to provide warnings in their package insert that the risk of suicide may be increased in depressed individuals (especially children) the first several weeks after beginning an antidepressant. However, studies have found that when more people in a community are taking antidepressants, the suicide rate is lower. The risk of suicide is inherent in depression and may persist until the individual responds to treatment. Depressed individuals who are at risk for suicide should be closely watched at the outset of therapy, and any signs of suicidal or violent behavior should be immediately reported to the physician or a mental health provider.

- **Warning:** Always let your physician or a family member know if you have suicidal thoughts. Notify your psychiatrist or your family physician whenever your depressive symptoms worsen or whenever you feel unable to control suicidal urges or thoughts.
- Do not discontinue Paxil abruptly. Your dosage should be gradually tapered before discontinuation to prevent any withdrawal symptoms.
- If you miss a dose, take it as soon as possible, within 2–3 hours of the scheduled dosing. If it is close to your next scheduled dose, skip the missed dose and continue on your regular dosing schedule, but do not take double doses.
- Paxil may be taken with or without food. Swallow tablets of Paxil-CR whole, and do not crush or chew the tablet.
- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of your medication.
- Keep your medication out of reach of children.

*If you have any questions about your medication, consult your physician or pharmacist.*

