



*If you or someone you know is in crisis, please call 911 and/or the toll-free National Suicide Prevention Lifeline at 800-273-TALK (8255) to speak with a trained crisis counselor 24/7. A help line and other resources are also available through the National Alliance on Mental Illness at [nami.org](http://nami.org).*

- **Paxil®**
  - Tablets (immediate release): 10 mg, 20 mg, 30 mg, 40 mg
  - Liquid suspension: 10 mg/5 mL
- **Paxil CR®**
  - Tablets (controlled release): 12.5 mg, 25 mg, 37.5 mg
- **Pexeva®**
  - Tablets (immediate release): 10 mg, 20 mg, 30 mg, 40 mg
- **Brisdelle®**
  - Capsule: 7.5 mg

## What is paroxetine and what does it treat?

Paroxetine is an antidepressant medication that works in the brain. It is approved for the treatment of major depressive disorder (MDD), generalized anxiety disorder (GAD), social anxiety disorder (social phobia), panic disorder, obsessive compulsive disorder (OCD), posttraumatic stress disorder (PTSD), and premenstrual dysphoric disorder (PMDD), and for vasomotor symptoms (hot flashes, night sweats, flushes, etc.) associated with menopause (Brisdelle®).

Symptoms of depression include:

- Depressed mood - feeling sad, empty, or tearful
- Feeling worthless, guilty, hopeless, and helpless
- Loss of interest or pleasure in your usual activities
- Sleep and eat more or less than usual (for most people it is less)
- Low energy, trouble concentrating, or thoughts of death (suicidal thinking)
- Psychomotor agitation ('nervous energy')
- Psychomotor retardation (feeling like you are moving and thinking in slow motion)
- Suicidal thoughts or behaviors

Generalized Anxiety Disorder (GAD) occurs when a person experiences excessive anxiety or worry for at least six months. Other symptoms include

- Restlessness
- Fatigue (low energy, feeling tired all the time)
- Difficulty concentrating
- Irritability
- Muscle tension
- Sleep disturbance (difficulty falling asleep or waking up in the middle of the night)

Obsessive Compulsive Disorder (OCD) occurs when a person experiences the following symptoms at the same time:

- Obsessions (unwanted, recurrent, and disturbing thoughts)
- Compulsions (repetitive, ritualized behaviors that the person feels driven to perform in order to lessen the anxiety produced by the obsession)

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

Panic Disorder occurs when a person experiences unexpected and repeated episodes of intense fear. These episodes have physical symptoms including chest pain, shortness of breath, heart palpitations, sweating, dizziness, and nausea. Fear of future episodes is also part of panic disorder.

PTSD occurs when a person experiences a traumatic event (e.g., assault, combat experience) and then later feels on edge; avoids situations that remind them of the event; and experiences flashbacks or nightmares.

Premenstrual dysphoric disorder (PMDD) is a condition where a woman experiences depression, tension, and irritability for a few days prior to menstruation that end when menstruation begins. These symptoms are more severe than those of premenstrual syndrome (PMS).

Social phobia/social anxiety disorder is a fear of situations where one may feel as if they are being judged by others. Symptoms include:

- Blushing
- Difficulty talking
- Nausea
- Sweating
- Shaking

Paroxetine may also be helpful when prescribed “off-label” for irritable bowel syndrome and obsessive-compulsive disorder in children. “Off-label” means that it hasn’t been approved by the Food and Drug Administration for this condition. Your mental health provider should justify his or her thinking in recommending any “off-label” treatment. They should be clear about the limits of the research around that medication and if there are any other options.

## What is the most important information I should know about paroxetine?

Do not stop taking paroxetine, even when you feel better. With input from you, your health care provider will assess how long you will need to take the medicine.

Missing doses of paroxetine may increase your risk for relapse in your symptoms.

Stopping paroxetine abruptly may result in one or more of the following withdrawal symptoms: irritability, nausea, feeling dizzy, vomiting, nightmares, headache, and/or paresthesias (prickling, tingling sensation on the skin).

Depression is also a part of bipolar illness. People with bipolar disorder who take antidepressants may be at risk for "switching" from depression into mania. Symptoms of mania include "high" or irritable mood, very high self-esteem, decreased need for sleep, pressure to keep talking, racing thoughts, being easily distracted, frequently involved in activities with a large risk for bad consequences (for example, excessive buying sprees).

Medical attention should be sought if serotonin syndrome is suspected. Please refer to serious side effects for signs/symptoms.

## Are there specific concerns about paroxetine and pregnancy?

If you are planning on becoming pregnant, notify your health care provider to best manage your medications. People living with MDD who wish to become pregnant face important decisions. Untreated MDD has risks to the fetus, as well as the mother. It is important to discuss the risks and benefits of treatment with your doctor and caregivers. Exposure of paroxetine to the fetus during the first trimester of pregnancy can increase the risk of cardiovascular malformations. For women who take antidepressant medications during weeks 13 through the end of their pregnancy (second and third trimesters), there is a risk that the baby can be born before it is fully developed (before 37 weeks).

For mothers who have taken SSRIs during their pregnancy, there appears to be less than a 1% chance of infants developing persistent pulmonary hypertension. This is a potentially fatal condition that is associated with use of the antidepressant in the second half of pregnancy. However, women who discontinued antidepressant therapy were five times more likely to have a depression relapse than those who continued their antidepressant. If you are pregnant, please discuss the risks and benefits of antidepressant use with your health care provider.

Caution is advised with breastfeeding since paroxetine does pass into breast milk.

## What should I discuss with my health care provider before taking paroxetine?

- Symptoms of your condition that bother you the most
- If you have thoughts of suicide or harming yourself
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you experience side effects from your medications, discuss them with your provider. Some side effects may pass with time, but others may require changes in the medication.
- Any other psychiatric or medical problems you have, including a history of bipolar disorder, bone problems, liver or kidney problems, bleeding or heart problems, glaucoma, low sodium in your blood or seizure disorder.
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies you have
- Other non-medication treatment you are receiving, such as talk therapy or substance abuse treatment. Your provider can explain how these different treatments work with the medication.
- If you are pregnant, plan to become pregnant, or are breastfeeding
- If you drink alcohol or use drugs

## How should I take paroxetine?

Paroxetine is usually taken one time per day with or without food.

Typically patients begin at a low dose of medicine and the dose is increased slowly over several weeks.

The dose usually ranges from 10 mg to 40 mg (75mg for controlled release). Only your health care provider can determine the correct dose for you.

If you are taking paroxetine for PMDD, it can be taken once daily (everyday) or intermittently (usually starting 14 days prior to menstruation through the first full day of menses of each cycle). Discuss this with your prescriber.

The liquid should be measured with a dosing spoon or oral syringe which you can get from your pharmacy.

The controlled release form as well as Pexeva® should be swallowed whole. They should not be chewed, crushed, or broken.

Consider using a calendar, pillbox, alarm clock, or cell phone alert to help you remember to take your medication. You may also ask a family member or friend to remind you or check in with you to be sure you are taking your medication.

## What happens if I miss a dose of paroxetine?

If you miss a dose of paroxetine, take it as soon as you remember, unless it is closer to the time of your next dose. Discuss this with your health care provider. Do not double your next dose or take more than what is prescribed.

## What should I avoid while taking paroxetine?

Avoid drinking alcohol or using illegal drugs while you are taking antidepressant medications. They may decrease the benefits (e.g., worsen your condition) and increase adverse effects (e.g., sedation) of the medication.

## What happens if I overdose with paroxetine?

If an overdose occurs, call your doctor or 911. You may need urgent medical care. You may also contact the poison control center at 1-800-222-1222.

A specific treatment to reverse the effects of paroxetine does not exist.

## What are the possible side effects of paroxetine?

### Common side effects

- Headache, nausea, constipation, diarrhea, dry mouth, increased sweating, and dizziness
- Feeling nervous, restless, fatigued, sleepy or having trouble sleeping (insomnia)

These will often improve over the first week or two as you continue to take the medication.

Sexual side effects, such as problems with orgasm or ejaculatory delay often do not diminish over time.

### Rare/serious side effects

Low sodium blood levels (symptoms of low sodium levels may include headache, weakness, difficulty concentrating and remembering), teeth grinding, angle closure glaucoma (symptoms of angle closure glaucoma may include eye pain, changes in vision, swelling or redness in or around eye),

Serotonin syndrome (symptoms may include shivering, diarrhea, confusion, severe muscle tightness, fever, seizures, and death), seizure

Discontinuation syndrome (abrupt discontinuation may include nausea, sweating, dysphoric mood, irritability, agitation, dizziness, sensory disturbances as electric shock sensations, tremor, anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, ringing in the ears, and seizures.

SSRI antidepressants including paroxetine may increase the risk of bleeding events. Combined use of aspirin, nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen), warfarin, and other anti-coagulants may increase this risk. This may include gums that bleed more easily, nosebleed, or gastrointestinal bleeding. Some cases have been life threatening.

Hypersensitivity to paroxetine. Call your health care provider if you get rash, hives, swelling, or difficulty breathing. Avoid with known hypersensitivity to paroxetine or any ingredients mixed with it.

## Are there any risks for taking paroxetine for long periods of time?

To date, there are no known problems associated with long term use of paroxetine. It is a safe and effective medication when used as directed.

## What other medications may interact with paroxetine?

Paroxetine should not be taken with or within two weeks of taking monoamine oxidase inhibitors (MAOIs). These include phenelzine (Nardil®), tranylcypromine (Parnate®), isocarboxazid (Marplan®), rasagiline (Azilect®), and selegiline (Emsam®).

Although rare, there is an increased risk of serotonin syndrome when paroxetine is used with other medications that increase serotonin, such as other antidepressants, buspirone (Buspar), lithium (Lithobid) migraine medications called “triptans” (e.g., Imitrex®), some pain medications (e.g., tramadol (Ultram®)), the antibiotic linezolid (Zyvox®), or intravenous methylene blue.

Paroxetine may increase the levels of:

- Atomoxetine (Strattera®)
- Antipsychotics, such as aripiprazole (Abilify®), risperidone (Risperdal®)
- Warfarin (Coumadin®)
- Cardiac medications such as propafenone (Rythmol®), metoprolol (Toprol XL®, Lopressor®) and propranolol (Inderal®)
- Tricyclic antidepressants, such as, desipramine (Norpramin®), imipramine (Tofranil®)

Combining paroxetine with thioridazine (Mellaril®), tamoxifen (Soltamox), pimozide (Orap) is not recommended.

Paroxetine may **increase** the effects of other medications that can cause bleeding (e.g., ibuprofen (Advil®, Motrin®), warfarin (Coumadin®) and aspirin).

## How long does it take for paroxetine to work?

Sleep, energy, or appetite may show some improvement within the first 1-2 weeks. Improvement in these physical symptoms can be an important early signal that the medication is working. Depressed mood and lack of interest in activities may need up to 6-8 weeks to fully improve.

## Summary of Black Box Warnings

### **Suicidal Thoughts or Actions in Children and Adults**

Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether they are taking antidepressant medications. This risk may persist until significant remission occurs.

In short-term studies, antidepressants increased the risk of suicidality in children, adolescents, and young adults when compared to placebo. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24. Adults age 65 and older taking antidepressants have a decreased risk of suicidality. Patients, their families, and caregivers should be alert to the emergence of anxiety, restlessness, irritability, aggressiveness and insomnia. If these symptoms emerge, they should be reported to the patient's prescriber or health care professional. All patients being treated with antidepressants for any indication should watch for and notify their health care provider for worsening symptoms, suicidality and unusual changes in behavior, especially during the first few months of treatment.

Paroxetine extended release is not approved for use in pediatric patients.

**Important Disclosure:** This information is being provided as a community outreach effort of the College of Psychiatric and Neurologic Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The College of Psychiatric and Neurologic Pharmacists disclaims any and all liability alleged as a result of the information provided herein.