

MEDICATION GUIDE

PAXIL® (PAX-il)

(paroxetine)

tablets

oral suspension

What is the most important information I should know about PAXIL?

PAXIL can cause serious side effects, including:

- **Increased risk of suicidal thoughts or actions.** PAXIL and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, especially within the **first few months of treatment or when the dose is changed. PAXIL is not for use in children.**

- **Depression or other mental illnesses are the most important causes of suicidal thoughts and actions.**

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts or feelings or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts or feelings or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

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

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

What is PAXIL?

PAXIL is a prescription medicine used in adults to treat:

- A certain type of depression called Major Depressive Disorder (MDD)
- Obsessive Compulsive Disorder (OCD)
- Panic Disorder (PD)
- Social Anxiety Disorder (SAD)
- Generalized Anxiety Disorder (GAD)
- Posttraumatic Stress Disorder (PTSD)

Do not take PAXIL if you:

- take a monoamine oxidase inhibitor (MAOI)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or the intravenous methylene blue
- are taking pimozide

- are taking thioridazine
- are allergic to paroxetine or any of the ingredients in PAXIL. See the end of this Medication Guide for a complete list of ingredients in PAXIL.

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI or one of these medicines, including the antibiotic linezolid or intravenous methylene blue.

Do not start taking an MAOI for at least 14 days after you stop treatment with PAXIL.

Before taking PAXIL, tell your healthcare provider about all your medical conditions, including if you:

- have heart problems
- have or had bleeding problems
- have, or have a family history of, bipolar disorder, mania or hypomania
- have or had seizures or convulsions
- have glaucoma (high pressure in the eye)
- have low sodium levels in your blood
- have bone problems
- have kidney or liver problems
- are pregnant or plan to become pregnant. PAXIL may harm your unborn baby. Talk to your healthcare provider about the risks to your unborn baby if you take PAXIL during pregnancy. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with PAXIL.
- are breastfeeding or plan to breastfeed. PAXIL passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with PAXIL.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

PAXIL and some other medicines may affect each other causing possible serious side effects. PAXIL may affect the way other medicines work and other medicines may affect the way PAXIL works.

Especially tell your healthcare provider if you take:

- medicines used to treat migraine headaches called triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- amphetamines
- St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin
- diuretics
- tamoxifen
- medicines used to treat mood, anxiety, psychotic, or thought disorders, including selective serotonin reuptake (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take PAXIL with your other medicines.

Do not start or stop any other medicines during treatment with PAXIL without talking to your healthcare provider first. Stopping PAXIL suddenly may cause you to have serious side effects. See, **“What are the possible side effects of PAXIL?”**

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take PAXIL?

- Take PAXIL exactly as prescribed. Your healthcare provider may need to change the dose of PAXIL until it is the right dose for you.
- Take PAXIL 1 time each day in the morning.
- PAXIL may be taken with or without food.
- If you are taking PAXIL oral suspension, shake the suspension well before taking.
- If you take too much PAXIL, call your poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are possible side effects of PAXIL?

PAXIL can cause serious side effects, including:

- See, **“What is the most important information I should know about PAXIL?”**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take PAXIL with certain other medicines. See, **“Who should not take PAXIL?”** **Call your healthcare provider or go to the nearest hospital emergency room right away** if you have any of the following signs and symptoms of serotonin syndrome:
 - agitation
 - seeing or hearing things that are not real (hallucinations)
 - confusion
 - coma
 - fast heart beat
 - changes in blood pressure
 - dizziness
 - sweating
 - flushing
 - high body temperature (hyperthermia)
 - shaking (tremors), stiff muscles, or muscle twitching
 - loss of coordination
 - seizures
 - nausea, vomiting, diarrhea
- **Eye problems (angle-closure glaucoma).** PAXIL may cause a type of eye problem called angle-closure glaucoma in people with certain other eye conditions. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are. Call your healthcare provider if you have eye pain, changes in your vision, or swelling or redness in or around the eye.
- **Medicine interactions.** Taking PAXIL with certain other medicines including thioridazine and pimozide may increase the risk of developing a serious heart problem called QT prolongation.
- **Seizures (convulsions).**
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take PAXIL. Symptoms may include:
 - greatly increased energy
 - racing thoughts
 - unusually grand ideas
 - talking more or faster than usual
 - severe problems sleeping
 - reckless behavior
 - excessive happiness or irritability
- **Discontinuation syndrome.** Suddenly stopping PAXIL may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
 - nausea
 - sweating
 - changes in your mood
 - irritability and agitation
 - electric shock feeling (paresthesia)
 - tremor
 - anxiety
 - confusion
 - tiredness
 - problems sleeping
 - hypomania
 - ringing in your ears (tinnitus)

- dizziness
- headache
- seizures

• **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood that may be serious and may cause death, can happen during treatment with PAXIL. Elderly people and people who take certain medicines may be at a greater risk for developing low sodium levels in your blood. Signs and symptoms may include:

- headache
- difficulty concentrating
- memory changes
- confusion
- weakness and unsteadiness on your feet which can lead to falls

In more severe or more sudden cases, signs and symptoms include:

- seeing or hearing things that are not real (hallucinations)
- fainting
- seizures
- coma
- stopping breathing (respiratory arrest)

• **Abnormal bleeding.** Taking PAXIL with aspirin, NSAIDs, or blood thinners may increase this risk. Tell your healthcare provider about any unusual bleeding or bruising.

• **Bone fractures.**

• **Sexual problems (dysfunction).** Taking selective serotonin reuptake inhibitors (SSRIs), including PAXIL, may cause sexual problems.

Symptoms in males may include:

- Delayed ejaculation or inability to have an ejaculation
- Decreased sex drive
- Problems getting or keeping an erection

Symptoms in females may include:

- Decreased sex drive
- Delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with PAXIL. There may be treatments your healthcare provider can suggest.

The most common side effects of PAXIL include:

- | | |
|--|-----------------------|
| • male and female sexual function problems | • weakness (asthenia) |
| • constipation | • decreased appetite |
| • diarrhea | • dizziness |
| • dry mouth | • infection |
| • problems sleeping | • nausea |
| • nervousness | • sleepiness |
| • sweating | • shaking (tremor) |
| • yawning | |

These are not all the possible side effects of PAXIL.

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

How should I store PAXIL?

- Store PAXIL tablets between 59°F to 86°F (15°C to 30°C).

- Store PAXIL oral suspension at or below 77°F (25°C).

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

General information about the safe and effective use of PAXIL.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take PAXIL for a condition for which it was not prescribed. Do not give PAXIL to other people, even if they have the same symptoms that you have. It may harm them. You may ask your healthcare provider or pharmacist for information about PAXIL that is written for healthcare professionals.

What are the ingredients in PAXIL?

Active ingredient: paroxetine hydrochloride

Inactive ingredients:

Tablets: dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, polyethylene glycols, polysorbate 80, sodium starch glycolate, titanium dioxide, and 1 or more of the following: D&C Red No. 30 aluminum lake, D&C Yellow No. 10 aluminum lake, FD&C Blue No. 2 aluminum lake, FD&C Yellow No. 6 aluminum lake

Oral suspension: citric acid (anhydrous), FD&C yellow No. 6, flavorings, glycerin, methylparaben, microcrystalline cellulose and carboxymethylcellulose sodium, polacrillin potassium, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion and sodium citrate (dihydrate)

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

Manufactured for: Apotex Corp.: Weston, Florida USA 33326

PAXIL® and PAXIL CR® are registered trademarks of the GlaxoSmithKline group of companies.

All other registered trademarks are the property of their respective owners.

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