

MEDICATION GUIDE

Paroxetine Tablets, USP

(pa rox' e teen)

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

Paroxetine tablets can cause serious side effects, including:

- **Increased risk of suicidal thoughts or actions.** Paroxetine tablets 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. Paroxetine tablets are 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:

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- 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
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What are paroxetine tablets?

Paroxetine tablets are 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 paroxetine tablets 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 paroxetine tablets. See the end of this medication guide for a complete list of ingredients in paroxetine tablets.

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 paroxetine tablets.

Before taking paroxetine tablets, 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. Paroxetine tablets may harm your unborn baby. Talk to your healthcare provider about the risks to your unborn baby if you take paroxetine tablets during pregnancy. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with paroxetine tablets.
- are breastfeeding or plan to breastfeed. Paroxetine passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with paroxetine tablets.

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

Paroxetine tablets and some other medicines may affect each other causing possible serious side effects. Paroxetine tablets may affect the way other medicines work and other medicines may affect the way paroxetine tablets 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 paroxetine tablets with your other medicines.

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

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 paroxetine tablets?

- Take paroxetine tablets exactly as prescribed. Your healthcare provider may need to change the dose of paroxetine tablets until it is the right dose for you.
- Take paroxetine tablets 1 time each day in the morning.
- Paroxetine tablets may be taken with or without food.
- If you take too much paroxetine tablets, 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 paroxetine tablets?

Paroxetine tablets can cause serious side effects, including:

- See, **“What is the most important information I should know about paroxetine tablets?”**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take paroxetine tablets with certain other medicines. See, **“who should not take paroxetine tablets?”** **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

○ sweating

- seeing or hearing things that are not real (hallucinations)
- flushing
- confusion
- high body temperature (hyperthermia)
- coma
- shaking (tremors), stiff muscles, or muscle twitching
- fast heart beat
- loss of coordination
- changes in blood pressure
- seizures
- dizziness
- nausea, vomiting, diarrhea

- **Eye problems (angle-closure glaucoma).** Paroxetine tablets 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 paroxetine tablets 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 paroxetine tablets. Symptoms may include:

- greatly increased energy
- severe problems sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

- **Discontinuation syndrome.** Suddenly stopping paroxetine tablets may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:

- nausea
- electric shock feeling (paresthesia)
- tiredness
- sweating
- tremor
- problems sleeping

- changes in your mood
- irritability and agitation
- dizziness
- anxiety
- confusion
- headache
- hypomania
- ringing in your ears (tinnitus)
- seizures

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- **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 paroxetine tablets. 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 paroxetine tablets 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 paroxetine, 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 paroxetine. There may be treatments your healthcare provider can suggest.

The most common side effects of paroxetine tablets include:

- male and female sexual function problems
 - constipation
 - diarrhea
 - dry mouth
 - problems sleeping
 - nervousness
 - sweating
 - yawning
 - weakness (asthenia)
 - decreased appetite
 - dizziness
 - infection
 - nausea
 - sleepiness
 - shaking (tremor)
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These are not all the possible side effects of paroxetine tablets.

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 paroxetine tablets?

- Store paroxetine tablets between 20° to 25°C (68° to 77°F).

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

General information about the safe and effective use of paroxetine tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take paroxetine tablets for a condition for which it was not prescribed. Do not give paroxetine tablets 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 paroxetine tablets that is written for healthcare professionals.

What are the ingredients in paroxetine tablets?

Active ingredient: paroxetine hydrochloride

Inactive ingredients:

Inactive ingredients in core tablets: dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, sodium starch glycolate.

Inactive ingredients in the coating of 10 mg tablets: ferric oxide red, ferric oxide yellow, ferrousferrous oxide, hypromellose, maltodextrin, medium-chain triglycerides, polydextrose, talc, titanium dioxide.

Inactive ingredients in the coating of 20 mg tablets: ferric oxide red, hypromellose, polyethylene glycol, titanium dioxide.

Inactive ingredients in the coating of 30 mg tablets: FD&C Blue No. 2 Aluminum Lake, hypromellose, polyethylene glycol, polysorbate 80, titanium dioxide.

Inactive ingredients in the coating of 40 mg tablets: FD&C Blue No. 1 Aluminum Lake, FD&C Red No. 40 Aluminum Lake, ferric oxide yellow, hypromellose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide.

Manufactured by:

Yiling Pharmaceutical Ltd

No.36, Zhujiang Road, Shijiazhuang, Hebei, 050035, China

Manufactured for:

Chartwell RX, LLC.

Congers, NY 10920

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

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