MEDICATION GUIDE
Paroxetine (pa rox` e tine)
Extended-Release Tablets, USP, for oral use

What is the most important information I should know about Paroxetine?
Paroxetine can cause serious side effects, including:

- **Increased risk of suicidal thoughts and actions.** Paroxetine and other antidepressant medicines may increase the risk of suicidal thoughts and actions in people 24 years of age and younger, especially within the **first few months of treatment or when the dose is changed. Paroxetine is not for use in children.**
  - **Depression or other mental illnesses are the most important causes of suicidal thoughts or 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.
  - Tell 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. Tell your healthcare provider between visits as needed, especially if you have concerns about symptoms.

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

  - suicide attempts
  - acting aggressive or violent
  - new or worse depression
  - feeling agitated, restless, angry, or irritable
  - an increase in activity or 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

See **"What are the possible side effects of Paroxetine?"** for more information about side effects.

What is Paroxetine?
Paroxetine is a prescription medicine used in adults to treat:

- A certain type of depression called major depressive disorder (MDD)
- Panic disorder
- Social anxiety disorder (SAD)
- Premenstrual dysphoric disorder (PMDD)

It is not known if Paroxetine is safe and effective in children.

Who should not take Paroxetine?
Do not take Paroxetine if you:

- are taking, or have stopped taking within the last 14 days, a medicine called a monoamine oxidase inhibitor (MAOI), including the antibiotic linezolid or intravenous methylene blue
- are taking certain medicines that can cause a heart rhythm problem called QT prolongation
- are allergic to paroxetine or any of the ingredients in Paroxetine. See the end of this Medication Guide for a complete list of ingredients in Paroxetine.

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI or one of these medicines.
Do not start taking an MAOI for at least 14 days after you stop treatment with Paroxetine.

Before taking Paroxetine, 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 high pressure in the eye (glaucoma)
- have low sodium levels in your blood
- have bone problems
- have kidney or liver problems

- are pregnant or plan to become pregnant. Paroxetine can harm your unborn baby.
    - Taking Paroxetine during your first trimester of pregnancy may cause your baby to be at an increased risk of having a heart problem (cardiac malformations) at birth.
    - Taking Paroxetine during your third trimester of pregnancy may cause your baby to have breathing, temperature, and feeding problems, low muscle tone, and irritability after birth and may cause your baby to be at an increased risk of a serious lung problem at birth. Talk to your healthcare provider about the risks to your unborn baby if you take Paroxetine during pregnancy.
    - You may be at increased risk for bleeding after childbirth if you take Paroxetine in the month before delivery.
    - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with Paroxetine.
    - There is a pregnancy registry for women who are exposed to Paroxetine during pregnancy. The purpose of the registry is to collect information about the health of women exposed to Paroxetine and their baby. If you become pregnant during treatment with Paroxetine, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-866-961-2388 or visit online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/.
- 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.
    - If you breastfeed during treatment with Paroxetine, tell your healthcare provider if your baby develops agitation, irritability, poor feeding, or poor weight gain.

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

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

Especially tell your healthcare provider if you take:

- medicines that can increase your risk for developing a serious problem called serotonin syndrome, including:
    - medicines used to treat migraine headaches called triptans
    - medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs), MAOIs, tricyclic antidepressants, lithium, buspirone
    - tramadol, fentanyl, meperidine, methadone, or other opioids
    - tryptophan
    - amphetamines
    - St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin, or other blood thinners
- diuretics
- tamoxifen

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 with your other medicines.

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

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?

- Take Paroxetine exactly as your healthcare provider tells you to. Your healthcare provider may need to change the dose of Paroxetine until it is the right dose for you.
- Take Paroxetine 1 time each day in the morning.
- Take Paroxetine with or without food.
- Swallow Paroxetine tablets whole. **Do not** chew or crush Paroxetine tablets.
- If you take too much Paroxetine, call your healthcare provider or poison help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are possible side effects of Paroxetine?

Paroxetine can cause serious side effects, including:

- See **"What is the most important information I should know about Paroxetine?"**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take Paroxetine with certain other medicines. See **"Who should not take Paroxetine?"** and **"Especially tell your healthcare provider if you take:" Tell your healthcare provider or go to the nearest hospital emergency room right away** if you develop 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
- **Medicine interactions that can lead to heart rhythm problems.** Taking Paroxetine with certain other medicines may increase the risk of developing a serious heart problem called QT prolongation. See **"Who should not take Paroxetine?"**
- **Increased risk of bleeding.** Taking Paroxetine with aspirin, NSAIDs, warfarin or other blood thinners may add to this risk. Tell your healthcare provider about any unusual bleeding or bruising.
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take Paroxetine. Tell your healthcare provider if you develop any symptoms of mania, which 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 Paroxetine 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
  - dizziness
  - electric shock feeling (paresthesia)
  - shaking (tremor)
  - anxiety
  - confusion
  - headache
  - tiredness
  - problems sleeping
  - hypomania
  - ringing in your ears (tinnitus)
  - seizures
- **Seizures (convulsions).**
- **Eye problems (angle-closure glaucoma).** Paroxetine 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. Tell your healthcare provider if you develop eye pain, changes in your vision, or swelling or redness in or around the eye.

- **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood that may be severe and may cause death, can happen during treatment with Paroxetine. Elderly people and people who take diuretics or become dehydrated may be at a greater risk for this. Signs and symptoms may include:
    - headache
    - difficulty concentrating
    - memory changes
    - confusion
    - weakness and unsteadiness which can lead to falls

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

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

The most common side effects Paroxetine include:

- male and female sexual function problems
- blurred vision
- weakness (asthenia)
- constipation
- decreased appetite
- diarrhea
- dizziness
- dry mouth
- problems sleeping
- nausea
- sleepiness
- sweating
- shaking (tremor)

Paroxetine may cause fertility problems in males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

Tell your healthcare provider or get emergency medical help right away if you develop an allergic reaction during treatment with Paroxetine such as rash, hives, swelling, or difficulty breathing.

These are not all the possible side effects of Paroxetine.
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?

- Store Paroxetine at room temperature between 68°F to 77°F (20°C to 25ºC).

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

General information about the safe and effective use of Paroxetine.

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

What are the ingredients in Paroxetine?
Active ingredient: paroxetine hydrochloride
Inactive ingredients: hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid and ethyl acrylate copolymer dispersion, polyethylene glycols, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide, triethyl citrate. In addition, the 25 mg and 37.5 mg colorant contains FD&C Blue No. 2 aluminum lake. In addition, the 25 mg colorant also contains carmine.

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For more information about Paroxetine call 1-844-834-0530.

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

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