

trimester, the physician should carefully consider the potential risks and benefits of treatment. The physician may consider tapering paroxetine in the third trimester.

**Dosage for Elderly or Debilitated, and Patients with Severe Renal or Hepatic Impairment:** The recommended initial dose is 10 mg/day for elderly patients, debilitated patients, and/or patients with severe renal or hepatic impairment. Increases may be made if indicated. Dosage should not exceed 40 mg/day.

**Switching Patients to or from a Monoamine Oxidase Inhibitor:** At least 14 days should elapse between discontinuation of a MAOI and initiation of paroxetine therapy. Similarly, at least 14 days should be allowed after stopping paroxetine before starting a MAOI.

**Discontinuation of Treatment with Paroxetine:** Symptoms associated with discontinuation of paroxetine have been reported (see PRECAUTIONS). Patients should be monitored for these symptoms when discontinuing treatment, regardless of the indication for which paroxetine is being prescribed. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

## HOW SUPPLIED

### Tablets:

Film-coated, modified-oval tablets as follows:

10 mg white tablets with the inscription POT 10 on one side.

NDC 68968-2010-1 Bottles of 30

20 mg dark orange tablets with the inscription POT 20 on one side.

The tablets are scored on both sides.

NDC 68968-2020-1 Bottles of 30

30 mg yellow tablets with the inscription POT 30 on one side.

NDC 68968-2030-1 Bottles of 30

40 mg rose tablets with the inscription POT 40 on one side.

NDC 68968-2040-1 Bottles of 30

**Protect from Humidity. Store at 25°C (77°F); excursions permitted to 15°-30°C (59° and 86°F) (see USP Controlled Room Temperature)**

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**R x o n l y**

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## Medication Guide

### Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal Thoughts or Actions

Read the Medication Guide that comes with you, or your family member's, antidepressant medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines. **Talk to your, or your family member's, healthcare provider about:**

- All risks and benefits of treatment with antidepressant medicines
- All treatment choices for depression or other serious mental illness

### What is the most important information I should know about antidepressant medicines, depression and other serious mental illnesses and suicidal thoughts or actions?

1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.
2. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions. These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?
  - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.

This is very important when an antidepressant medicine is started or when the dose is changed.

- Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

**Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:**

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling very agitated or restless
- Panic attacks
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry, or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood

**What else do I need to know about antidepressant medicines?**

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.

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