

1306 10-mg yellow, scored tablets engraved on the front with PAXIL and on the back with 10.
1307 NDC 0029-3210-13 Bottles of 30
1308 20-mg pink, scored tablets engraved on the front with PAXIL and on the back with 20.
1309 NDC 0029-3211-13 Bottles of 30
1310 NDC 0029-3211-59 Bottles of 90
1311 NDC 0029-3211-21 SUP 100s (intended for institutional use only)
1312 30-mg blue tablets engraved on the front with PAXIL and on the back with 30.
1313 NDC 0029-3212-13 Bottles of 30
1314 40-mg green tablets engraved on the front with PAXIL and on the back with 40.
1315 NDC 0029-3213-13 Bottles of 30
1316 Store tablets between 15° and 30°C (59° and 86°F).
1317 **Oral Suspension:** Orange-colored, orange-flavored, 10 mg/5 mL, in 250 mL white bottles.
1318 NDC 0029-3215-48
1319 Store suspension at or below 25°C (77°F).
1320 PAXIL is a registered trademark of GlaxoSmithKline.
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Medication Guide

Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and Suicidal

Thoughts or Actions

PAXIL® (PAX-il) (paroxetine hydrochloride) Tablets and Oral Suspension

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1328 Read the Medication Guide that comes with your or your family member’s antidepressant
1329 medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with
1330 antidepressant medicines. **Talk to your, or your family member’s, healthcare provider**
1331 **about:**

- 1332 • All risks and benefits of treatment with antidepressant medicines
- 1333 • 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 action?

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1338 **1. Antidepressant medicines may increase suicidal thoughts and actions in some children,**
1339 **teenagers, and young adults within the first few months of treatment.**
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- 1341 **2. Depression and other serious mental illnesses are the most important causes of suicidal**
1342 **thoughts and actions. Some people may have a particularly high risk of having suicidal**
1343 **thoughts or actions.** These include people who have (or have a family history of) bipolar
1344 illness (also called manic-depressive illness) or suicidal thoughts or actions.
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- 1346 **3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a**

- 1347 **family member?**
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- Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant 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.

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1356 **Call a healthcare provider right away if you or your family member has any of the**

1357 **following symptoms, especially if they are new, worse, or worry you:**

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- 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

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1371 **What else do I need to know about antidepressant medicines?**

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- **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 risk 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**

1390 **in children.** Talk to your child's healthcare provider for more information.

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1392 This Medication Guide has been approved by the U.S. Food and Drug Administration for all
1393 antidepressants.

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1398 Research Triangle Park, NC 27709

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