

The following product is manufactured and distributed by Eli Lilly and Company:

Prozac[®] Weekly[™] Capsules are available in:

The 90-mg¹ capsule is an opaque green cap and clear body containing discretely visible white pellets through the clear body of the capsule, imprinted with Lilly on the cap and 3004 and 90 mg on the body.

NDC 0002-3004-75 (PU3004) - Blister package of 4

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1326 ¹ Fluoxetine base equivalent.1327 ² Protect from light.1328 ³ Dispense in a tight, light-resistant container.

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1330 Store at Controlled Room Temperature, 15° to 30°C (59° to 86°F).

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ANIMAL TOXICOLOGY

1332 Phospholipids are increased in some tissues of mice, rats, and dogs given fluoxetine
1333 chronically. This effect is reversible after cessation of fluoxetine treatment. Phospholipid
1334 accumulation in animals has been observed with many cationic amphiphilic drugs, including
1335 fenfluramine, imipramine, and ranitidine. The significance of this effect in humans is unknown.

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Medication Guide

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

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1345 Read the Medication Guide that comes with your or your family member's antidepressant
1346 medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with
1347 antidepressant medicines. **Talk to your, or your family member's, healthcare provider**
1348 **about:**

- 1349 • all risks and benefits of treatment with antidepressant medicines
- 1350 • 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?

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1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.

1356 **2. Depression and other serious mental illnesses are the most important causes of**
 1357 **suicidal thoughts and actions. Some people may have a particularly high risk of**
 1358 **having suicidal thoughts or actions.** These include people who have (or have a family
 1359 history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or
 1360 actions.

1361 **3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a**
 1362 **family member?**

1363 • Pay close attention to any changes, especially sudden changes, in mood, behaviors,
 1364 thoughts, or feelings. This is very important when an antidepressant medicine is
 1365 started or when the dose is changed.

1366 • Call the healthcare provider right away to report new or sudden changes in mood,
 1367 behavior, thoughts, or feelings.

1368 • Keep all follow-up visits with the healthcare provider as scheduled. Call the
 1369 healthcare provider between visits as needed, especially if you have concerns about
 1370 symptoms.

1371 **Call a healthcare provider right away if you or your family member has any of the**
 1372 **following symptoms, especially if they are new, worse, or worry you:**

- 1373 • thoughts about suicide or dying
- 1374 • attempts to commit suicide
- 1375 • new or worse depression
- 1376 • new or worse anxiety
- 1377 • feeling very agitated or restless
- 1378 • panic attacks
- 1379 • trouble sleeping (insomnia)
- 1380 • new or worse irritability
- 1381 • acting aggressive, being angry, or violent
- 1382 • acting on dangerous impulses
- 1383 • an extreme increase in activity and talking (mania)
- 1384 • other unusual changes in behavior or mood

What else do I need to know about antidepressant medicines?

1385 • **Never stop an antidepressant medicine without first talking to a healthcare provider.**
 1386 Stopping an antidepressant medicine suddenly can cause other symptoms.
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1388 • **Antidepressants are medicines used to treat depression and other illnesses.** It is
 1389 important to discuss all the risks of treating depression and also the risks of not treating it.
 1390 Patients and their families or other caregivers should discuss all treatment choices with the
 1391 healthcare provider, not just the use of antidepressants.

- 1392 • **Antidepressant medicines have other side effects.** Talk to the healthcare provider about
1393 the side effects of the medicine prescribed for you or your family member.
- 1394 • **Antidepressant medicines can interact with other medicines.** Know all of the medicines
1395 that you or your family member takes. Keep a list of all medicines to show the healthcare
1396 provider. Do not start new medicines without first checking with your healthcare provider.
- 1397 • **Not all antidepressant medicines prescribed for children are FDA approved for use in**
1398 **children.** Talk to your child's healthcare provider for more information.

1399 *This Medication Guide has been approved by the US Food and Drug Administration for*
1400 *all antidepressants.*

1401 Patient Information revised June 21, 2007

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