



1257 **100 mg Extended-Release Capsules:** Available in a two-piece gelatin capsule (dark blue
 1258 opaque cap/white opaque body) imprinted with  on one side of the cap and LCR 100 on the
 1259 other side of the cap.

1260 Bottles of 30 NDC 68727-600-01

1261
 1262 **150 mg Extended-Release Capsules:** Available in a two-piece gelatin capsule (dark blue
 1263 opaque cap/powder blue opaque body) imprinted with  on one side of the cap and LCR 150
 1264 on the other side of the cap.

1265 Bottles of 30 NDC 68727-601-01

1266
 1267 Storage

1268 LUVOX CR Capsules should be protected from high humidity and stored at 25°C (77°F);
 1269 excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].
 1270 Avoid exposure to temperatures above 30°C (86°F).

1271
 1272 Dispense in tight containers.

1273
 1274 **Keep out of reach of children.**

1275 Lotronex™ is a trademark of GlaxoSmithKline

1276 LUVOX® is a registered trademark of Solvay Pharmaceuticals, Inc.

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 1278 Distributed by:

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 1280 **Jazz Pharmaceuticals, Inc.**

1281 Palo Alto, CA 94304

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 1283 LCR-PI-01 Rev 0607

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1288 Medication Guide

1289 Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal 1290 Thoughts or Actions

1291

1292 Read the Medication Guide that comes with your or your family member's antidepressant
 1293 medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with
 1294 antidepressant medicines. **Talk to your, or your family member's, healthcare provider**
 1295 **about:**

1296

- 1297 • all risks and benefits of treatment with antidepressant medicines
- 1298 • all treatment choices for depression or other serious mental illness

1299

1300 **What is the most important information I should know about antidepressant medicines,**
 1301 **depression and other serious mental illnesses, and suicidal thought or actions?**

1302

- 1303 **1. Antidepressant medicines may increase suicidal thoughts and actions in some**
 1304 **children, teenagers, and young adults within in the first few months of treatment.**
 1305 **2. Depression and other serious mental illnesses are the most important causes of**
 1306 **suicidal thoughts and actions. Some people may have a particularly high risk of**
 1307 **having suicidal thoughts or actions.** These include people who have (or have a family
 1308 history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts and
 1309 actions.
 1310 **3. How can I watch for and try to prevent suicidal thoughts and actions in myself or**
 1311 **family member?**
- 1312 • Pay close attention to any changes, especially sudden changes, in mood,
 1313 behaviors, thoughts, or feelings. This is very important when an antidepressant
 1314 medicine is started or when the dose is changed.
 - 1315 • Call the healthcare provider right away to report new or sudden changes in mood,
 1316 behavior, thoughts, or feelings.
 - 1317 • Keep all follow-up visits with the healthcare provider as scheduled. Call the
 1318 healthcare provider between visits as needed, especially if you have concerns about
 1319 symptoms.

1320 **Call a healthcare provider right away if you or your family member has any of the**
 1321 **following symptoms, especially if they are new, worse, or worry you:**

- 1322
- 1323 • thoughts about suicide or dying
- 1324 • attempts to commit suicide
- 1325 • new or worse depression
- 1326 • new or worse anxiety
- 1327 • feeling very agitated or restless
- 1328 • panic attacks
- 1329 • trouble sleeping (insomnia)
- 1330 • new or worse irritability
- 1331 • acting aggressive, being angry, or violent
- 1332 • acting on dangerous impulses
- 1333 • an extreme increase in activity and talking (mania)
- 1334 • other unusual changes in behavior or mood
- 1335

1336 **What else do I need to know about antidepressant medicines?**

- 1337 • **Never stop an antidepressant medicine without first talking to a healthcare**
 1338 **provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- 1339 • **Antidepressants are medicines used to treat depression and other illnesses.** It is
 1340 important to discuss all the risks of treating depression and also the risks of not
 1341 treating it. Patients and their families or other caregivers should discuss all treatment
 1342 choices with the healthcare provider, not just the use of antidepressants.
- 1343 • **Antidepressant medicines have other side effects.** Talk to the healthcare provider
 1344 about the side effects of the medicine prescribed for you or your family member.
- 1345 • **Antidepressant medicines can interact with other medicines.** Know all of the
 1346 medicines that you or your family member takes. Keep a list of all medicines to show

1347 the healthcare provider. Do not start new medicines without first checking with your
1348 healthcare provider.

1349 • **Not all antidepressant medicines prescribed for children are FDA approved for**
1350 **use in children.** Talk to your child's healthcare provider for more information.

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1352 This Medication Guide has been approved by the U.S. Food and Drug Administration for all
1353 antidepressants.

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1355 **Jazz Pharmaceuticals, Inc.**

1356 Palo Alto, CA 94304

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