

1268 meningitis such as headache, fever, nausea, vomiting, stiff neck, rash, abnormal sensitivity to
1269 light, myalgia, chills, confusion, or drowsiness while taking LAMICTAL XR.

1270 **17.10 Potential Medication Errors**

1271 Medication errors involving LAMICTAL have occurred. In particular the names
1272 LAMICTAL or lamotrigine can be confused with the names of other commonly used
1273 medications. Medication errors may also occur between the different formulations of
1274 LAMICTAL. To reduce the potential of medication errors, write and say LAMICTAL XR
1275 clearly. Depictions of the LAMICTAL XR Extended-Release Tablets can be found in the
1276 Medication Guide. Each LAMICTAL XR tablet has a distinct color and white center, and is
1277 printed with “LAMICTAL XR” and the tablet strength. These distinctive features serve to
1278 identify the different presentations of the drug and thus may help reduce the risk of medication
1279 errors. LAMICTAL XR is supplied in round, unit-of-use bottles with orange caps containing 30
1280 tablets. The label on the bottle includes a depiction of the tablets that further communicates to
1281 patients and pharmacists that the medication is LAMICTAL XR and the specific tablet strength
1282 included in the bottle. The unit-of-use bottle with a distinctive orange cap and distinctive bottle
1283 label features serves to identify the different presentations of the drug and thus may help to
1284 reduce the risk of medication errors. **To avoid a medication error of using the wrong drug or
1285 formulation, patients should be strongly advised to visually inspect their tablets to verify
1286 that they are LAMICTAL XR each time they fill their prescription and to immediately talk
1287 to their doctor/pharmacist if they receive a LAMICTAL XR tablet without a white center
1288 and without “LAMICTAL XR” and the strength printed on the tablet as they may have
1289 received the wrong medication [see Dosage Forms and Strengths (3), How Supplied/Storage
1290 and Handling (16)].**

1291
1292 LAMICTAL XR and DiffCORE are trademarks of GlaxoSmithKline.

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MEDICATION GUIDE

1307 **LAMICTAL[®] (la-MIK-tal) XR[™] (lamotrigine) Extended-Release Tablets**
1308

1309 Read this Medication Guide before you start taking LAMICTAL XR and each time you get a
1310 refill. There may be new information. This information does not take the place of talking with
1311 your healthcare provider about your medical condition or treatment. If you have questions about
1312 LAMICTAL XR, ask your healthcare provider or pharmacist.

1313

1314 **What is the most important information I should know about LAMICTAL XR?**

1315 **1. LAMICTAL XR may cause a serious skin rash that may cause you to be hospitalized or**
1316 **to stop LAMICTAL XR; it may rarely cause death.**

1317 There is no way to tell if a mild rash will develop into a more serious reaction. These serious
1318 skin reactions are more likely to happen when you begin taking LAMICTAL XR, within the
1319 first 2 to 8 weeks of treatment. But it can happen in people who have taken LAMICTAL XR
1320 for any period of time. Children between 2 to 16 years of age have a higher chance of getting
1321 this serious skin reaction while taking lamotrigine. LAMICTAL XR is not approved for use
1322 in children less than 13 years of age.

1323 The risk of getting a rash is higher if you:

- 1324 • take LAMICTAL XR while taking valproate [DEPAKENE (valproic acid) or
1325 DEPAKOTE (divalproex sodium)].
1326 • take a higher starting dose of LAMICTAL XR than your healthcare provider prescribed.
1327 • increase your dose of LAMICTAL XR faster than prescribed.

1328 **LAMICTAL XR can also cause other types of allergic reactions or serious problems**
1329 **that may affect organs and other parts of your body like the liver or blood cells. You**
1330 **may or may not have a rash with these types of reactions.**

1331 **Call your healthcare provider right away if you have any of the following:**

- 1332 • **a skin rash**
1333 • **hives**
1334 • **fever**
1335 • **swollen lymph glands**
1336 • **painful sores in the mouth or around your eyes**
1337 • **swelling of your lips or tongue**
1338 • **yellowing of your skin or eyes**
1339 • **unusual bruising or bleeding**
1340 • **severe fatigue or weakness**
1341 • **severe muscle pain**
1342 • **frequent infections**

1343 These symptoms may be the first signs of a serious reaction. A healthcare provider should
1344 examine you to decide if you should continue taking LAMICTAL XR.

1345 **2. Like other antiepileptic drugs, LAMICTAL XR may cause suicidal thoughts or actions**
1346 **in a very small number of people, about 1 in 500.**

1347 **Call a healthcare provider right away if you have any of these symptoms, especially if**
1348 **they are new, worse, or worry you:**

- 1349 • thoughts about suicide or dying
- 1350 • attempt to commit suicide
- 1351 • new or worse depression
- 1352 • new or worse anxiety
- 1353 • feeling agitated or restless
- 1354 • panic attacks
- 1355 • trouble sleeping (insomnia)
- 1356 • new or worse irritability
- 1357 • acting aggressive, being angry, or violent
- 1358 • acting on dangerous impulses
- 1359 • an extreme increase in activity and talking (mania)
- 1360 • other unusual changes in behavior or mood

1361 **Do not stop LAMICTAL XR without first talking to a healthcare provider.**

- 1362 • Stopping LAMICTAL XR suddenly can cause serious problems.
- 1363 • Suicidal thoughts or actions can be caused by things other than medicines. If you have
1364 suicidal thoughts or actions, your healthcare provider may check for other causes.

1365 **How can I watch for early symptoms of suicidal thoughts and actions?**

- 1366 • Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or
1367 feelings.
- 1368 • Keep all follow-up visits with your healthcare provider as scheduled.
- 1369 • Call your healthcare provider between visits as needed, especially if you are worried
1370 about symptoms.

1371 **3. LAMICTAL XR may rarely cause aseptic meningitis, a serious inflammation of the**
1372 **protective membrane that covers the brain and spinal cord.**

1373 **Call your healthcare provider right away if you have any of the following symptoms:**

- 1374 • Headache
- 1375 • Fever
- 1376 • Nausea
- 1377 • Vomiting
- 1378 • Stiff neck
- 1379 • Rash
- 1380 • Unusual sensitivity to light
- 1381 • Muscle pains
- 1382 • Chills

- 1383 • Confusion
- 1384 • Drowsiness

1385 Meningitis has many causes other than LAMICTAL XR, which your doctor would check for
1386 if you developed meningitis while taking LAMICTAL XR.

1387 **LAMICTAL XR can have other serious side effects.** For more information ask your
1388 healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect
1389 that bothers you. Be sure to read the section below entitled “What are the possible side
1390 effects of LAMICTAL XR?”

1391 **4. Patients prescribed LAMICTAL have sometimes been given the wrong medicine**
1392 **because many medicines have names similar to LAMICTAL, so always check that you**
1393 **receive LAMICTAL XR.**

1394 Taking the wrong medication can cause serious health problems. When your healthcare
1395 provider gives you a prescription for LAMICTAL XR:

- 1396 • Make sure you can read it clearly.
- 1397 • Talk to your pharmacist to check that you are given the correct medicine.
- 1398 • Each time you fill your prescription, check the tablets you receive against the pictures of
1399 the tablets below.

1400 These pictures show the distinct wording, colors, and shapes of the tablets that help to
1401 identify the right strength of LAMICTAL XR. Immediately call your pharmacist if you
1402 receive a LAMICTAL XR tablet that does not look like one of the tablets shown below, as
1403 you may have received the wrong medication.

1404
1405

LAMICTAL XR (lamotrigine) Extended-Release Tablets

 <p>25 mg, yellow with white center</p> <p>Imprinted with LAMICTAL XR 25</p>	 <p>50 mg, green with white center</p> <p>Imprinted with LAMICTAL XR 50</p>	 <p>100 mg, orange with white center</p> <p>Imprinted with LAMICTAL XR 100</p>
 <p>200 mg, blue with white center</p> <p>Imprinted with LAMICTAL XR 200</p>	 <p>250 mg, purple with white center</p> <p>Imprinted with LAMICTAL XR 250</p>	 <p>300 mg, gray with white center</p> <p>Imprinted with LAMICTAL XR 300</p>

1406

1407 **What is LAMICTAL XR?**

1408 LAMICTAL XR is a prescription medicine used:

- 1409 • together with other medicines to treat primary generalized tonic-clonic seizures and partial
1410 onset seizures in people 13 years of age and older.
1411 • alone to treat partial seizures when changing from certain other medicines used in people 13
1412 years and older.

1413 It is not known if LAMICTAL XR is safe or effective in children less than 13 years of age. Other
1414 forms of lamotrigine can be used in children aged 2 to 12 years.

1415

1416 **Who should not take LAMICTAL XR?**

1417 You should not take LAMICTAL XR if you have had an allergic reaction to lamotrigine or to
1418 any of the inactive ingredients in LAMICTAL XR. See the end of this leaflet for a complete list
1419 of ingredients in LAMICTAL XR.

1420

1421 **What should I tell my healthcare provider before taking LAMICTAL XR?**

1422 Before taking LAMICTAL XR, tell your healthcare provider about all of your medical
1423 conditions, including if you:

- 1424 • have had a rash or allergic reaction to another antiseizure medicine.
1425 • have or have had depression, mood problems, or suicidal thoughts or behavior.
1426 • are taking oral contraceptives (birth control pills) or other female hormonal medicines. Do
1427 not start or stop taking birth control pills or other female hormonal medicine until you have
1428 talked with your healthcare provider. Tell your healthcare provider if you have any changes
1429 in your menstrual pattern such as breakthrough bleeding. Stopping these medicines may
1430 cause side effects (such as dizziness, lack of coordination, or double vision). Starting these
1431 medicines may lessen how well LAMICTAL XR works.
1432 • are pregnant or plan to become pregnant. It is not known if LAMICTAL XR will harm your
1433 unborn baby. If you become pregnant while taking LAMICTAL XR, talk to your healthcare
1434 provider about registering with the North American Antiepileptic Drug Pregnancy Registry.
1435 You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to
1436 collect information about the safety of antiepileptic drugs during pregnancy.
1437 • are breastfeeding. LAMICTAL XR passes into breast milk and may cause side effects in a
1438 breastfed baby. If you breastfeed while taking LAMICTAL XR, watch your baby closely for
1439 trouble breathing, episodes of temporarily stopping breathing, sleepiness, or poor sucking.
1440 Call your baby's healthcare provider right away if you see any of these problems. Talk to
1441 your healthcare provider about the best way to feed your baby if you take LAMICTAL XR.

1442 Tell your healthcare provider about all the medicines you take or if you are planning to take a
1443 new medicine, including prescription and non-prescription medicines, vitamins, and herbal

1444 supplements. Using LAMICTAL XR with certain other medicines can affect each other, causing
1445 side effects.

1446

1447 **How should I take LAMICTAL XR?**

- 1448 • Take LAMICTAL XR exactly as prescribed.
- 1449 • Your healthcare provider may change your dose. Do not change your dose without talking to
1450 your healthcare provider.
- 1451 • Do not stop taking LAMICTAL XR without talking to your healthcare provider. Stopping
1452 LAMICTAL XR suddenly may cause serious problems. For example, if you have epilepsy
1453 and you stop taking LAMICTAL XR suddenly, you may get seizures that do not stop. Talk
1454 with your healthcare provider about how to stop LAMICTAL XR slowly.
- 1455 • If you miss a dose of LAMICTAL XR, take it as soon as you remember. If it is almost time
1456 for your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not**
1457 **take 2 doses at the same time.**
- 1458 • You may not feel the full effect of LAMICTAL XR for several weeks.
- 1459 • If you have epilepsy, tell your healthcare provider if your seizures get worse or if you have
1460 any new types of seizures.
- 1461 • LAMICTAL XR can be taken with or without food.
- 1462 • Do not chew, crush, or divide LAMICTAL XR.
- 1463 • Swallow LAMICTAL XR tablets whole.
- 1464 • If you have trouble swallowing LAMICTAL XR Tablets, tell your healthcare provider
1465 because there may be another form of lamotrigine you can take.
- 1466 • If you receive LAMICTAL XR in a blisterpack, examine the blisterpack before use. Do not
1467 use if blisters are torn, broken, or missing.

1468

1469 **What should I avoid while taking LAMICTAL XR?**

1470 Do not drive a car or operate complex, hazardous machinery until you know how LAMICTAL
1471 XR affects you.

1472

1473 **What are possible side effects of LAMICTAL XR?**

- 1474 • See “What is the most important information I should know about LAMICTAL XR?”
1475 Common side effects of LAMICTAL XR include:
- 1476 • Dizziness
- 1477 • Tremor
- 1478 • Double vision
- 1479 • Nausea
- 1480 • Vomiting
- 1481 • Trouble with balance and coordination
- 1482 • Anxiety

1483 Other common side effects that have been reported with another form of lamotrigine include
1484 headache, sleepiness, blurred vision, runny nose, and rash.

1485 Tell your healthcare provider about any side effect that bothers you or that does not go away.
1486 These are not all the possible side effects of LAMICTAL XR. For more information, ask your
1487 healthcare provider or pharmacist.

1488 Call your doctor for medical advice about side effects. You may report side effects to FDA at
1489 1-800-FDA-1088.

1490

1491 **How should I store LAMICTAL XR?**

- 1492 • Store LAMICTAL XR at room temperature between 59°F to 86°F (15°C to 30°C).
- 1493 • **Keep LAMICTAL XR and all medicines out of the reach of children.**

1494

1495 **General information about LAMICTAL XR**

1496 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
1497 Do not use LAMICTAL XR for a condition for which it was not prescribed. Do not give
1498 LAMICTAL XR to other people, even if they have the same symptoms you have. It may harm
1499 them.

1500 This Medication Guide summarizes the most important information about LAMICTAL XR. If
1501 you would like more information, talk with your healthcare provider. You can ask your
1502 healthcare provider or pharmacist for information about LAMICTAL XR that is written for
1503 healthcare professionals.

1504 For more information, go to www.lamictalxr.com or call 1-888-825-5249.

1505

1506 **What are the ingredients in LAMICTAL XR?**

1507 Active ingredient: Lamotrigine.

1508 Inactive ingredients: glycerol monostearate, hypromellose, lactose monohydrate, magnesium
1509 stearate, methacrylic acid copolymer dispersion, polyethylene glycol 400, polysorbate 80, silicon
1510 dioxide (25- and 50-mg tablets only), titanium dioxide, triethyl citrate, carmine (250-mg tablet
1511 only), iron oxide black (50-, 250-, and 300-mg tablets only), iron oxide yellow (25-, 50-, 100-mg
1512 tablets only), iron oxide red (100-mg tablet only), FD&C Blue No. 2 Aluminum Lake (200- and
1513 250-mg tablets only). Tablets are printed with edible black ink.

1514

1515 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**

1516

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1518 DEPAKENE and DEPAKOTE are registered trademarks of Abbott Laboratories.

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