

1612 **using the wrong drug or formulation, patients should be strongly advised to visually**
1613 **inspect their tablets to verify that they are LAMICTAL, as well as the correct formulation**
1614 **of LAMICTAL, each time they fill their prescription** [*see Dosage Forms and Strengths (3.1,*
1615 *3.2, 3.3), How Supplied/Storage and Handling (16)*].

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1617 LAMICTAL is a registered trademark of GlaxoSmithKline.
1618 Microcaps and AdvaTab are registered trademarks of Eurand, Inc.

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1621
1622 GlaxoSmithKline
1623 Research Triangle Park, NC 27709

1624
1625 LAMICTAL Tablets and Chewable Dispersible Tablets are manufactured by
1626 DSM Pharmaceuticals, Inc., Greenville, NC 27834 or
1627 GlaxoSmithKline, Research Triangle Park, NC 27709

1628
1629 LAMICTAL Orally Disintegrating Tablets are manufactured by
1630 Eurand, Inc., Vandalia, OH 45377

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1634
1635 Month Year
1636 LMT:xPI

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1638 MEDICATION GUIDE

1639
1640 **LAMICTAL[®] (la-MIK-tal) (lamotrigine) Tablets and Chewable Dispersible Tablets**
1641 **LAMICTAL[®] ODT[™] (lamotrigine) Orally Disintegrating Tablets**

1642
1643 Read this Medication Guide before you start taking LAMICTAL and each time you get a refill.
1644 There may be new information. This information does not take the place of talking with your
1645 healthcare provider about your medical condition or treatment. If you have questions about
1646 LAMICTAL, ask your healthcare provider or pharmacist.

1647

1648 **What is the most important information I should know about LAMICTAL?**

1649 **1. LAMICTAL may cause a serious skin rash that may cause you to be hospitalized or to**
1650 **stop LAMICTAL; it may rarely cause death.**

1651 There is no way to tell if a mild rash will develop into a more serious reaction. These serious
1652 skin reactions are more likely to happen when you begin taking LAMICTAL, within the first
1653 2 to 8 weeks of treatment. But it can happen in people who have taken LAMICTAL for any
1654 period of time. Children between 2 to 16 years of age have a higher chance of getting this
1655 serious skin reaction while taking LAMICTAL.

1656 The risk of getting a rash is higher if you:

- 1657 • take LAMICTAL while taking valproate [DEPAKENE (valproic acid) or DEPAKOTE
- 1658 (divalproex sodium)].
- 1659 • take a higher starting dose of LAMICTAL than your healthcare provider prescribed
- 1660 • increase your dose of LAMICTAL faster than prescribed.

1661 **LAMICTAL can also cause other types of allergic reactions or serious problems which**
1662 **may affect organs and other parts of your body like the liver or blood cells. You may or**
1663 **may not have a rash with these types of reactions.**

1664 **Call your healthcare provider right away if you have any of the following:**

- 1665 • a skin rash
- 1666 • hives
- 1667 • fever
- 1668 • swollen lymph glands
- 1669 • painful sores in the mouth or around your eyes
- 1670 • swelling of your lips or tongue
- 1671 • yellowing of your skin or eyes
- 1672 • unusual bruising or bleeding
- 1673 • severe fatigue or weakness
- 1674 • severe muscle pain
- 1675 • frequent infections

1676 These symptoms may be the first signs of a serious reaction. A healthcare provider should
1677 examine you to decide if you should continue taking LAMICTAL.

1678 **2. Like other antiepileptic drugs, LAMICTAL may cause suicidal thoughts or actions in a**
1679 **very small number of people, about 1 in 500.**

1680 **Call a healthcare provider right away if you have any of these symptoms, especially if**
1681 **they are new, worse, or worry you:**

- 1682 • thoughts about suicide or dying
- 1683 • attempt to commit suicide
- 1684 • new or worse depression
- 1685 • new or worse anxiety

- 1686 • feeling agitated or restless
- 1687 • panic attacks
- 1688 • trouble sleeping (insomnia)
- 1689 • new or worse irritability
- 1690 • acting aggressive, being angry, or violent
- 1691 • acting on dangerous impulses
- 1692 • an extreme increase in activity and talking (mania)
- 1693 • other unusual changes in behavior or mood

1694 **Do not stop LAMICTAL without first talking to a healthcare provider.**

- 1695 • Stopping LAMICTAL suddenly can cause serious problems.
- 1696 • Suicidal thoughts or actions can be caused by things other than medicines. If you have
- 1697 suicidal thoughts or actions, your healthcare provider may check for other causes.

1698 **How can I watch for early symptoms of suicidal thoughts and actions?**

- 1699 • Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or
- 1700 feelings.
- 1701 • Keep all follow-up visits with your healthcare provider as scheduled.
- 1702 • Call your healthcare provider between visits as needed, especially if you are worried
- 1703 about symptoms.

1704 **3. LAMICTAL may rarely cause aseptic meningitis, a serious inflammation of the**

1705 **protective membrane that covers the brain and spinal cord.**

1706 **Call your healthcare provider right away if you have any of the following symptoms:**

- 1707 • Headache
- 1708 • Fever
- 1709 • Nausea
- 1710 • Vomiting
- 1711 • Stiff neck
- 1712 • Rash
- 1713 • Unusual sensitivity to light
- 1714 • Muscle pains
- 1715 • Chills
- 1716 • Confusion
- 1717 • Drowsiness

1718 Meningitis has many causes other than LAMICTAL, which your doctor would check for if

1719 you developed meningitis while taking LAMICTAL.

1720 **LAMICTAL can have other serious side effects.** For more information ask your healthcare

1721 provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers

1722 you. Be sure to read the section below entitled “What are the possible side effects of
 1723 LAMICTAL?”





1724 **4. Patients prescribed LAMICTAL have sometimes been given the wrong medicine**
 1725 **because many medicines have names similar to LAMICTAL, so always check that you**
 1726 **receive LAMICTAL.**

1727 Taking the wrong medication can cause serious health problems. When your healthcare
 1728 provider gives you a prescription for LAMICTAL:




- 1729 • Make sure you can read it clearly.
- 1730 • Talk to your pharmacist to check that you are given the correct medicine.
- 1731 • Each time you fill your prescription, check the tablets you receive against the pictures of
 1732 the tablets below.

1733 These pictures show the distinct wording, colors, and shapes of the tablets that help to
 1734 identify the right strength of LAMICTAL Tablets, Chewable Dispersible Tablets, and
 1735 Orally Disintegrating Tablets. Immediately call your pharmacist if you receive a
 1736 LAMICTAL tablet that does not look like one of the tablets shown below, as you may
 1737 have received the wrong medication.





1738 **LAMICTAL (lamotrigine) Tablets**

 25 mg, white Imprinted with LAMICTAL 25	 100 mg, peach Imprinted with LAMICTAL 100	 150 mg, cream Imprinted with LAMICTAL 150	 200 mg, blue Imprinted with LAMICTAL 200
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1739 **LAMICTAL (lamotrigine) Chewable Dispersible Tablets**

 2 mg, white Imprinted with LTG 2	 5 mg, white Imprinted with GX CL2	 25 mg, white Imprinted with GX CL5
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1740 **LAMICTAL ODT (lamotrigine) Orally Disintegrating Tablets**

 25 mg, white to off-white	 50 mg, white to off-white	 100 mg, white to off-white	 200 mg, white to off-white
---	---	--	--

Imprinted with LMT on one side 25 on the other	Imprinted with LMT on one side 50 on the other	Imprinted with LAMICTAL on one side 100 on the other	Imprinted with LAMICTAL on one side 200 on the other
---	---	---	---

1741

1742 **What is LAMICTAL?**

1743 LAMICTAL is a prescription medicine used:

- 1744 1. together with other medicines to treat certain types of seizures (partial seizures, primary
1745 generalized tonic-clonic seizures, generalized seizures of Lennox-Gastaut syndrome) in
1746 people 2 years or older.
- 1747 2. alone when changing from other medicines used to treat partial seizures in people 16 years or
1748 older.
- 1749 3. for the long-term treatment of Bipolar I Disorder to lengthen the time between mood
1750 episodes in people 18 years or older who have been treated for mood episodes with other
1751 medicine.

1752 It is not known if LAMICTAL is safe or effective in children or teenagers under the age of 18
1753 with mood disorders such as bipolar disorder or depression.

1754 It is not known if LAMICTAL is safe or effective when used alone as the first treatment of
1755 seizures in adults.

1756

1757 **Who should not take LAMICTAL?**

1758 You should not take LAMICTAL if you have had an allergic reaction to lamotrigine or to any of
1759 the inactive ingredients in LAMICTAL. See the end of this leaflet for a complete list of
1760 ingredients in LAMICTAL.

1761

1762 **What should I tell my healthcare provider before taking LAMICTAL?**

1763 Before taking LAMICTAL, tell your healthcare provider about all of your medical conditions,
1764 including if you:

- 1765 • have had a rash or allergic reaction to another antiseizure medicine.
- 1766 • have or have had depression, mood problems or suicidal thoughts or behavior.
- 1767 • are taking oral contraceptives (birth control pills) or other female hormonal medicines. Do
1768 not start or stop taking birth control pills or other female hormonal medicine until you have
1769 talked with your healthcare provider. Tell your healthcare provider if you have any changes
1770 in your menstrual pattern such as breakthrough bleeding. Stopping or starting these
1771 medicines may cause side effects (such as dizziness, lack of coordination, or double vision)
1772 or lessen how well LAMICTAL works.

- 1773 • are pregnant or plan to become pregnant. It is not known if LAMICTAL will harm your
1774 unborn baby. If you become pregnant while taking LAMICTAL, talk to your healthcare
1775 provider about registering with the North American Antiepileptic Drug Pregnancy Registry.
1776 You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to
1777 collect information about the safety of antiepileptic drugs during pregnancy.
- 1778 • are breastfeeding. LAMICTAL passes into breast milk and may cause side effects in a
1779 breastfed baby. If you breastfeed while taking LAMICTAL, watch your baby closely for
1780 trouble breathing, episodes of temporarily stopping breathing, sleepiness, or poor sucking.
1781 Call your baby's healthcare provider right away if you see any of these problems. Talk to
1782 your healthcare provider about the best way to feed your baby if you take LAMICTAL.

1783 Tell your healthcare provider about all the medicines you take or if you are planning to take a
1784 new medicine, including prescription and non-prescription medicines, vitamins, and herbal
1785 supplements. Using LAMICTAL with certain other medicines can affect each other, causing side
1786 effects.

1787

1788 **How should I take LAMICTAL?**

- 1789 • Take LAMICTAL exactly as prescribed.
- 1790 • Your healthcare provider may change your dose. Do not change your dose without talking to
1791 your healthcare provider.
- 1792 • Do not stop taking LAMICTAL without talking to your healthcare provider. Stopping
1793 LAMICTAL suddenly may cause serious problems. For example, if you have epilepsy and
1794 you stop taking LAMICTAL suddenly, you may get seizures that do not stop. Talk with your
1795 healthcare provider about how to stop LAMICTAL slowly.
- 1796 • If you miss a dose of LAMICTAL, take it as soon as you remember. If it is almost time for
1797 your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not**
1798 **take two doses at the same time.**
- 1799 • You may not feel the full effect of LAMICTAL for several weeks.
- 1800 • If you have epilepsy, tell your healthcare provider if your seizures get worse or if you have
1801 any new types of seizures.
- 1802 • Swallow LAMICTAL tablets whole.
- 1803 • If you have trouble swallowing LAMICTAL Tablets, there may be another form of
1804 LAMICTAL you can take.
- 1805 • LAMICTAL ODT should be placed on the tongue and moved around the mouth. The tablet
1806 will rapidly disintegrate, can be swallowed with or without water, and can be taken with or
1807 without food.
- 1808 • LAMICTAL Chewable Dispersible tablets may be swallowed whole, chewed, or mixed in
1809 water or diluted fruit juice. If the tablets are chewed, drink a small amount of water or diluted
1810 fruit juice to help in swallowing. To break up LAMICTAL Chewable Dispersible tablets, add
1811 the tablets to a small amount of liquid (1 teaspoon, or enough to cover the medicine) in a

1812 glass or spoon. Wait at least 1 minute or until the tablets are completely broken up, mix the
1813 solution together and take the whole amount right away.
1814 • If you receive LAMICTAL in a blisterpack, examine the blisterpack before use. Do not use if
1815 blisters are torn, broken, or missing.

1816
1817 **What should I avoid while taking LAMICTAL?**

1818 • Do not drive a car or operate complex, hazardous machinery until you know how
1819 LAMICTAL affects you.

1820
1821 **What are possible side effects of LAMICTAL?**

1822 • See “What is the most important information I should know about LAMICTAL?”

1823 Common side effects of LAMICTAL include:

• dizziness	• tremor
• headache	• rash
• blurred or double vision	• fever
• lack of coordination	• abdominal pain
• sleepiness	• back pain
• nausea, vomiting	• tiredness
• insomnia	• dry mouth

1824 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1825 These are not all the possible side effects of LAMICTAL. For more information, ask your
1826 healthcare provider or pharmacist.

1827 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-
1828 800-FDA-1088.

1829

1830 **How should I store LAMICTAL?**

1831 • Store LAMICTAL at room temperature between 68°F to 77°F (20°C to 25°C).

1832 • **Keep LAMICTAL and all medicines out of the reach of children.**

1833

1834 **General information about LAMICTAL**

1835 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

1836 Do not use LAMICTAL for a condition for which it was not prescribed. Do not give

1837 LAMICTAL to other people, even if they have the same symptoms you have. It may harm them.

1838 This Medication Guide summarizes the most important information about LAMICTAL. If you
1839 would like more information, talk with your healthcare provider. You can ask your healthcare
1840 provider or pharmacist for information about LAMICTAL that is written for healthcare
1841 professionals.

1842 For more information, go to www.lamictal.com or call 1-888-825-5249.

1843

1844 **What are the ingredients in LAMICTAL?**

1845 **LAMICTAL Tablets**

1846 Active ingredient: lamotrigine.

1847 Inactive ingredients: lactose; magnesium stearate, microcrystalline cellulose, povidone, sodium
1848 starch glycolate, FD&C Yellow No. 6 Lake (100-mg tablet only), ferric oxide, yellow (150-mg
1849 tablet only), and FD&C Blue No. 2 Lake (200-mg tablet only).

1850 **LAMICTAL Chewable Dispersible Tablets**

1851 Active ingredient: lamotrigine.

1852 Inactive ingredients: blackcurrant flavor, calcium carbonate, low-substituted
1853 hydroxypropylcellulose, magnesium aluminum silicate, magnesium stearate, povidone, saccharin
1854 sodium, and sodium starch glycolate.

1855 **LAMICTAL ODT Orally Disintegrating Tablets**

1856 Active ingredient: lamotrigine.

1857 Inactive ingredients: artificial cherry flavor, crospovidone, ethylcellulose, magnesium stearate,
1858 mannitol, polyethylene, and sucralose.

1859

1860 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**

1861

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