MEDICATION GUIDE

Lamotrigine (lam-OH-try-jeen)

Tablets for Oral Suspension USP (Chewable Dispersible Tablets)

R_x only

Phenylketonurics: Phenylalanine is a component of aspartame. Each lamotrigine tablets for oral suspension (chewable dispersible tablets) 5 mg and 25 mg contains 1.4 mg and 0.98 mg of phenylalanine, respectively.

What is the most important information I should know about lamotrigine tablets for oral suspension (chewable dispersible tablets)?

1. **Lamotrigine tablets for oral suspension (chewabale dispersible tablets) may cause a serious skin rash that may cause you to be hospitalized or even cause death.**

   There is no way to tell if a mild rash will become more serious. A serious skin rash can happen at any time during your treatment with lamotrigine tablets for oral suspension (chewable dispersible tablets), but is more likely to happen within the first 2 to 8 weeks of treatment. Children and teenagers aged between 2 to and 17 years have a higher chance of getting this serious skin rash while taking lamotrigine tablets for oral suspension (chewable dispersible tablets).

   The risk of getting a rash is higher if you:

   - take lamotrigine tablets for oral suspension (chewable dispersible tablets) while taking valproate (DEPAKENE(valproic acid) or DEPAKOTE (divalproex sodium)).
   - take a higher starting dose of lamotrigine tablets for oral suspension (chewable dispersible tablets) than your healthcare provider prescribed.
   - increase your dose of lamotrigine tablets for oral suspension (chewable dispersible tablets) faster than prescribed.

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

   - **a skin rash**
   - **blistering or peeling of your skin**
   - **hives**
   - **painful sores in your mouth or around your eyes**

   These symptoms may be the first signs of a serious skin reaction. A healthcare provider should examine you to decide if you should continue taking lamotrigine tablets for oral suspension (chewable dispersible tablets).

2. **Other serious reactions, including serious blood problems or liver problems.** Lamotrigine tablets for oral suspension (chewable dispersible tablets) can also cause other types of allergic reactions or serious problems that may affect organs and other parts of your body like your liver or blood cells. You may or may not have a rash with these types of reactions. Call your healthcare provider right away if you have any of these symptoms:

   - fever
   - frequent infections
   - severe muscle pain
   - swelling of your face, eyes, lips, or tongue
   - swollen lymph glands
   - unusual bruising or bleeding
   - weakness, fatigue
   - yellowing of your skin or the white part of your eyes

3. **Like other antiepileptic drugs, lamotrigine tablets for oral suspension (chewable dispersible tablets) may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

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

   - thoughts about suicide or dying
   - attempt to commit suicide
   - new or worse depression
   - new or worse anxiety
   - feeling 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

Do not stop lamotrigine tablets for oral suspension (chewable dispersible tablets) without first talking to a healthcare provider.

- Stopping lamotrigine tablets for oral suspension (chewable dispersible tablets) suddenly can cause serious problems.
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions in myself or a family member?

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

4. **Lamotrigine tablets for oral suspension (chewable dispersible tablets) may cause aseptic meningitis, a serious inflammation of the protective membrane that covers the brain and spinal cord.**

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

   - headache
   - fever
   - nausea
   - vomiting
   - stiff neck
   - rash
   - unusual sensitivity to light
   - muscle pains
   - chills
   - confusion
   - drowsiness

   Meningitis has many causes other than lamotrigine tablets for oral suspension (chewable dispersible tablets), which your doctor would check for if you developed meningitis while taking lamotrigine tablets for oral suspension (chewable dispersible tablets).

   Lamotrigine tablets for oral suspension (chewable dispersible tablets) can cause other serious side effects. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you. Be sure to read the section below entitled "What are the possible side effects of lamotrigine tablets for oral suspension (chewable dispersible tablets)?"

5. **People prescribed lamotrigine tablets for oral suspension (chewable dispersible tablets) have sometimes been given the wrong medicine because many medicines have names similar to lamotrigine tablets for oral suspension (chewable dispersible tablets), so always check that you receive lamotrigine tablets for oral suspension (chewable dispersible tablets).**

   Taking the wrong medication can cause serious health problems. "When your healthcare provider" gives you a prescription for lamotrigine tablets for oral suspension (chewable dispersible tablets)**:**

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

   These pictures show the distinct wording, colors, and shapes of the tablets that help to identify the right strength of lamotrigine tablets for oral suspension (chewable dispersible tablets). Immediately call your pharmacist if you receive a lamotrigine tablets for oral suspension (chewable dispersible tablets) that does not look like one of the tablets shown below, as you may have received the wrong medication.

 5 mg white to off-white debossed with L217	 25 mg white to off-white debossed with 218 on one side and L on other side.

What is lamotrigine tablet for oral suspension (chewable dispersible tablet)?

- Lamotrigine tablet for oral suspension (chewable dispersible tablet) is a prescription medicine used:
  - o together with other medicines to treat certain types of seizures (partial-onset seizures, primary generalized tonic-clonic seizures, generalized seizures of Lennox-Gastaut syndrome) in people aged 2 years and older.
  - o alone when changing from 1 other medicine used to treat partial-onset seizures in people aged 16 years and older.
  - o for the long-term treatment of bipolar I disorder to lengthen the time between mood episodes in people who have been treated for mood episodes with other medicine.

- It is not known if lamotrigine tablet for oral suspension (chewable dispersible tablet) is safe or effective in people younger than 18 years with mood episode such as bipolar disorder or depression.
- It is not known if lamotrigine tablets for oral suspension (chewable dispersible tablets) are safe or effective when used alone as the first treatment of seizures.
- It is not known if lamotrigine tablets for oral suspension (chewable dispersible tablets) are safe or effective for people with mood episodes who have not already been treated with other medicines.

Lamotrigine tablets for oral suspension (chewable dispersible tablets) should not be used for acute treatment of manic or mixed mood episodes.

Do not take lamotrigine tablets for oral suspension (chewable dispersible tablets):

- If you have had an allergic reaction to lamotrigine or to any of the inactive ingredients in lamotrigine tablets for oral suspension (chewable dispersible tablets). See the end of this leaflet for a complete list of ingredients in lamotrigine tablets for oral suspension (chewable dispersible tablets).

Before taking lamotrigine tablets for oral suspension (chewable dispersible tablets), tell your healthcare provider about all of your health conditions, including if you:

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

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Lamotrigine tablets for oral suspension (chewable dispersible tablets) and certain other medicines may interact with each other. This may cause serious side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take lamotrigine tablets for oral suspension (chewable dispersible tablets)?

- Take lamotrigine tablets for oral suspension (chewable dispersible tablets) exactly as prescribed.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Do not stop taking lamotrigine tablets for oral suspension (chewable dispersible tablets) without talking to your healthcare provider. Stopping lamotrigine tablets for oral suspension (chewable dispersible tablets) suddenly may cause serious problems. For example, if you have epilepsy and you stop taking lamotrigine tablets for oral suspension (chewable dispersible tablets) suddenly, you may have seizures that do not stop. Talk with your healthcare provider about how to stop lamotrigine tablets for oral suspension (chewable dispersible tablets) slowly.
- If you miss a dose of lamotrigine tablets for oral suspension (chewable dispersible tablets), take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. **Do not take 2 doses at the same time.**
- If you take too much lamotrigine tablets for oral suspension (chewable dispersible tablets), call your healthcare provider or your local Poison Control Center or go to the nearest hospital emergency room right away.
- You may not feel the full effect of lamotrigine tablets for oral suspension (chewable dispersible tablets) for several weeks.
- If you have epilepsy, tell your healthcare provider if your seizures get worse or if you have any new types of seizures.
- Lamotrigine tablets for oral suspension (chewable dispersible tablets) may be swallowed whole, chewed, or mixed in water or diluted fruit juice. If the tablets are chewed, drink a small amount of water or diluted fruit juice to help in swallowing. To break up lamotrigine tablets for oral suspension (chewable dispersible tablets), add the tablets to a small amount of liquid (1 teaspoon, or enough to cover the medicine) in a glass or spoon. Wait at least 1 minute or until the tablets are completely broken up, mix the solution together and take the whole amount right away.

What should I avoid while taking lamotrigine tablets for oral suspension (chewable dispersible tablets)?

Do not drive, operate machinery or do other dangerous activities until you know how lamotrigine tablets for oral suspension (chewable dispersible tablets) affects you.

What are the possible side effects of lamotrigine tablets for oral suspension (chewable dispersible tablets)?

Lamotrigine tablets for oral suspension (chewable dispersible tablets) can cause serious side effects.

See "What is the most important information I should know about lamotrigine tablets for oral suspension (chewable dispersible tablets)?"

Common side effects of lamotrigine tablets for oral suspension (chewable dispersible tablets) include:

- dizziness
- tremor
- headache
- rash
- blurred or double vision
- fever
- lack of coordination
- abdominal pain
- infections, including seasonal flu
- sleepiness
- back pain
- nausea, vomiting
- diarrhea
- tiredness
- insomnia
- dry mouth
- stuffy nose
- sore throat

These are not all the possible side effects of lamotrigine tablets for oral suspension (chewable dispersible tablets).

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

How should I store lamotrigine tablets for oral suspension (chewable dispersible tablets)?

- Store at 20 to 25°C (68 to 77°F) excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].
- **Keep lamotrigine tablets for oral suspension (chewable dispersible tablets) and all medicines out of the reach of children.**

General information about the safe and effective use of lamotrigine tablets for oral suspension (chewable dispersible tablets)

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lamotrigine tablets for oral suspension (chewable dispersible tablets) for a condition for which it was not prescribed. Do not give lamotrigine tablets for oral suspension (chewable dispersible tablets) to other people, even if they have the same symptoms that you have. It may harm them.

If you take a urine drug screening test, lamotrigine tablets for oral suspension (chewable dispersible tablets)may make the test result positive for another drug. If you require a urine drug screening test, tell the healthcare professional administering the test that you are taking lamotrigine tablets for oral suspension (chewable dispersible tablets).

You can ask your healthcare provider or pharmacist for information about lamotrigine tablets for oral suspension (chewable dispersible tablets) that is written for health professionals.

For more information about lamotrigine tablets for oral suspension (chewable dispersible tablets), call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in lamotrigine tablets for oral suspension (chewable dispersible tablets)?

Lamotrigine tablets for oral suspension (chewable dispersible tablets)

Active ingredient: lamotrigine.

Inactive ingredients: mannitol, crospovidone, povidone K-30, microcrystalline cellulose, aspartame, black currant flavor, colloidal silicon dioxide, magnesium stearate and talc.

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

Medication Guide available at http://www.alembicusa.com/medicationguide.aspx or call 1-866-210-9797.

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Revised: 09/2019

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