MEDICATION GUIDE
SUBVENITE (Sub-VE-nite) lamotrigine tablets, USP

What is the most important information I should know about SUBVENITE?

1. **SUBVENITE 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 SUBVENITE, but is more likely to happen within the first 2 to 8 weeks of treatment. Children and teenagers aged between 2 and 17 years have a higher chance of getting this serious skin rash while taking SUBVENITE.

   The risk of getting a serious skin rash is higher if you:
   - take SUBVENITE while taking valproate [DEPAKENE (valproic acid) or DEPAKOTE (divalproex sodium)].
   - take a higher starting dose of SUBVENITE than your healthcare provider prescribed.
   - increase your dose of SUBVENITE faster than prescribed.

   The risk of serious skin reactions may be associated with a variant in genes called HLA-B*1502 in people from Asian origin (mainly of Han Chinese and Thai origin). See, **"Before taking SUBVENITE, tell your healthcare provider about all of your health conditions".**

   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 SUBVENITE.
2. **Other serious reactions, including serious blood problems or liver problems.**
   SUBVENITE 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, looking pale
   - weakness, fatigue
   - yellowing of your skin or the white part of your eyes
   - trouble walking or seeing
   - seizures for the first time or happening more often
   - pain and/or tenderness in the area towards the top of your stomach (enlarged liver and/or spleen)
3. In patients with known heart problems, the use of SUBVENITE may lead to a fast heart beat. Call your healthcare provider right away if you:
   - have a fast, slow, or pounding heart beat.
   - feel your heart skip a beat.
   - have shortness of breath.
   - have chest pain.
   - feel lightheaded.
4. **Like other antiepileptic drugs, SUBVENITE may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

   Call a 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 SUBVENITE without first talking to a healthcare provider.
   - Stopping SUBVENITE 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.
5. **SUBVENITE 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 SUBVENITE, which your doctor would check for if you developed meningitis while taking SUBVENITE.

   SUBVENITE 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 SUBVENITE?"
6. **People prescribed SUBVENITE have sometimes been given the wrong medicine because many medicines have names similar to SUBVENITE, so always check that you receive SUBVENITE.**

   Taking the wrong medication can cause serious health problems. When your healthcare provider gives you a prescription for SUBVENITE:
   - 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 SUBVENITE tablets. Immediately call your pharmacist if you receive a SUBVENITE tablet that does not look like one of the tablets shown below, as you may have received the wrong medication.

   SUBVENITE (lamotrigine) tablets

Tablet Strength	SUBVENITE Dimensional Drawing
25 mg	L2 UPPER FACE / LOWER FACE
100 mg	10LA UPPER FACE / LOWER FACE
150 mg	15LA UPPER FACE / LOWER FACE
200 mg	20LA UPPER FACE / LOWER FACE

What is SUBVENITE?
- SUBVENITE is a prescription medicine used:
  - 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.
  - alone when changing from 1 other medicine used to treat partial-onset seizures in people aged 16 years and older.
  - 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 SUBVENITE is safe or effective in people younger than 18 years with mood episodes such as bipolar disorder or depression.
- It is not known if SUBVENITE is safe or effective when used alone as the first treatment of seizures.
- It is not known if SUBVENITE is safe or effective for people with mood episodes who have not already been treated with other medicines.
- SUBVENITE should not be used for acute treatment of manic or mixed mood episodes.

Do not take SUBVENITE:
- if you have had an allergic reaction to lamotrigine or to any of the inactive ingredients in SUBVENITE. See the end of this leaflet for a complete list of ingredients in SUBVENITE.

Before taking SUBVENITE, tell your healthcare provider about all of your health conditions, including if you:
- have had a rash or allergic reaction to another antiseizure medicine.
- are of Asian origin, have had HLA testing before, and know you are carrying the genetic variant, HLA-B*1502.
- have or have had depression, mood problems, or suicidal thoughts or behavior.
- have a history of heart problems or irregular heart beats or any of your family members have any heart problem, including genetic abnormalities.
- have had aseptic meningitis after taking SUBVENITE.
- are taking estrogen-containing products, including oral contraceptives (birth control pills) or other female hormonal medicines (such as hormone replacement therapy). 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 SUBVENITE may cause side effects (such as dizziness, lack of coordination, or double vision). Starting these medicines may lessen how well SUBVENITE works.
- are pregnant or plan to become pregnant. It is not known if SUBVENITE may harm your unborn baby. If you become pregnant while taking SUBVENITE, 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 SUBVENITE, 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 SUBVENITE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SUBVENITE 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 SUBVENITE?
- Take SUBVENITE 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 SUBVENITE without talking to your healthcare provider.
  Stopping SUBVENITE suddenly may cause serious problems. For example, if you have epilepsy and you stop taking SUBVENITE suddenly, you may have seizures that do not stop. Talk with your healthcare provider about how to stop SUBVENITE slowly.
- If you miss a dose of SUBVENITE, 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 SUBVENITE, 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 SUBVENITE 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.
- Swallow SUBVENITE whole.
- If you have trouble swallowing SUBVENITE tablets, tell your healthcare provider because there may be another form of SUBVENITE you can take.
- If you receive SUBVENITE in a blister pack, examine the blister pack before use. Do not use if blisters are torn, broken, or missing.

What should I avoid while taking SUBVENITE?

Do not drive, operate machinery, or do other dangerous activities until you know how SUBVENITE affects you.

What are the possible side effects of SUBVENITE?

SUBVENITE can cause serious side effects.

See "What is the most important information I should know about SUBVENITE?"

Common side effects of SUBVENITE 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 SUBVENITE.

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 SUBVENITE?
- Store SUBVENITE at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Keep SUBVENITE and all medicines out of the reach of children.

General information about the safe and effective use of SUBVENITE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SUBVENITE for a condition for which it was not prescribed. Do not give SUBVENITE 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, SUBVENITE 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 SUBVENITE.

You can ask your healthcare provider or pharmacist for information about SUBVENITE that is written for health professionals.

For more information, call 1-800-273-6729.

What are the ingredients in SUBVENITE?

Active ingredient: lamotrigine, USP.

Inactive ingredients: lactose monohydrate; magnesium stearate; microcrystalline cellulose; povidone; and sodium starch glycolate.

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OWP® | The Pharmaceutical Social Enterprise®

Manufactured by:
Torrent Pharmaceuticals LTD., India.
Manufactured for:
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