**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. Call your healthcare provider if you become 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 (DEPAKEN, divalproex sodium),
- have a higher starting dose of SUBVENITE than your healthcare provider prescribed,
- increase your dose of SUBVENITE 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
- 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, especially if you are younger than age 25.**

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worsen, 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 that is not normal for you
- 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 had suicidal thoughts or actions, your healthcare provider your healthcare provider may check for a condition called depression.

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

**If you have any of the following symptoms,**

- 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 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?**

1. **SUBVENITE can be taken with or without food.**

2. **Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.**

3. **Do not stop taking SUBVENITE without talking to your healthcare provider.**

**What is SUBVENITE?**

SUBVENITE is a prescription medicine used:

- 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 to SUBVENITE tablets that have been used in people aged 16 years and older.

**Subcutaneous injection:**

- do not use if blisters are torn, broken, or missing.

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

**O/W P Pharmaceuticals, Inc.,**

**Manufactured by:**

**TORTORI PHARMACEUTICALS LTD., INDIA.**

**Supersedes A/W No.:**

**8082161**

**Revised May 2021**

**53x103**