SUBVENE (Sub-V-e-ne) Iambotinamide tablets, USP

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

1. SUBVENE 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 SUBVENE, but is more likely to happen within the first 2 to 6 weeks of treatment. Children and teenagers aged 2 to 17 years have a higher chance of getting this serious skin rash while taking SUBVENE.

2. The risk of getting a serious skin rash is higher if:
   - you take SUBVENE while taking valproate (DEPAKENe or DEPAKOTE (divalproex sodium)).
   - you have a serious skin rash from SUBVENE while you are taking another antiepileptic medicine (such as valproate, divalproex sodium, or topiramate).
   - you have a skin rash from taking another antiepileptic medicine (such as valproate, divalproex sodium, or topiramate).

3. SUBVENE may cause asthma or other serious allergic reactions. Call yourAU healthcare provider right away if you have any of these symptoms, especially if they are new, worsen, or occur without an infection:
   - 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

4. SUBVENE may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

5. Do not stop SUBVENE without talking to your healthcare provider.

6. The most common side effects of SUBVENE include:
   - headache
   - dizziness
   - tremor
   - sleepiness
   - fatigue
   - decreased appetite
   - rash
   - nausea
   - vomiting
   - constipation
   - diarrhea
   - confusion
   - nervousness
   - pruritus (itching)
   - fluid retention

7. SUBVENE is not safe or effective for people with mood episodes who have not already been treated with another antiepileptic medicine. SUBVENE should not be used for acute treatment of mania or mixed mood episodes.

Do not take SUBVENE:

1. if you have had an allergic reaction to lamotrigine or any of the inactive ingredients in SUBVENE. See the end of this leaflet for a complete list of ingredients in SUBVENE.

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

- have a rash or allergic reaction to another antiepileptic medicine.
- have or had depression, mood problems, suicidal thoughts or behavior, or bipolar disorder.

What are the possible side effects of SUBVENE?

SUBVENE can cause serious side effects. See "What is the most important information I should know about SUBVENE?" for more information on important side effects.

Common side effects of SUBVENE include:
- dizziness
- tremor
- sleepiness
- fatigue
- constipation
- diarrhea
- confusion
- nervousness
- fluid retention

These are all the possible side effects of SUBVENE. For more information, ask your healthcare provider or pharmacist.

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

What should I store SUBVENE at?

- Store SUBVENE 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 SUBVENE and all medicines out of the reach of children.

How should I store SUBVENE?

- Store the tablets at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]

- Do not stop taking SUBVENE without talking to your healthcare provider. Stopping SUBVENE suddenly may cause serious problems. For example, if you have epilepsy and you stop taking SUBVENE suddenly, you may have seizures that do not stop. Talk with your healthcare provider about how to stop taking SUBVENE slowly.

- If you have a history of severe allergic reactions or if you are allergic to lamotrigine, USP, or any other ingredient in SUBVENE, do not take SUBVENE. Call your healthcare provider right away if you experience any of the following symptoms:

What are the ingredients in SUBVENE? (Iambotinamide) tablets, USP

SUBVENE tablets, tolbutamide, USP

What are the inactive ingredients in SUBVENE? (Iambotinamide) tablets, USP

Active ingredient: Iambotinamide, USP

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

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

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90700785

Revised August 2016