

**MEDICATION GUIDE**  
**MYSOLINE ( My-so- lean)**  
**(primidone)**  
**Tablets**

Read this Medication Guide before you start taking MYSOLINE and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

**What is the most important information I should know about MYSOLINE?**  
**Do not stop taking MYSOLINE without first talking to your healthcare provider.**  
Stopping MYSOLINE suddenly can cause serious problems.

**MYSOLINE can cause serious side effects, including:**

**1. Like other antiepileptic drugs, MYSOLINE 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
- attempts 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

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

- 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.

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

- Stopping MYSOLINE suddenly can cause serious problems. Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

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.

**What is MYSOLINE?**

MYSOLINE is a prescription medicine used alone or with other medicines to treat people with:

- generalized tonic-clonic (grand mal) seizures
- complex partial (psychomotor) seizures
- partial (focal) epileptic seizures.

**Who should not take MYSOLINE?**

Do not take MYSOLINE if you:

- have a genetic disorder called porphyria
- are allergic to phenobarbital

**What should I tell my healthcare provider before taking MYSOLINE?**

Before you take MYSOLINE, tell your healthcare provider if you:

- have or have had depression, mood problems or suicidal thoughts or behavior
- have any other medical conditions
- are pregnant or planning to become pregnant. MYSOLINE may harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking MYSOLINE. You and your healthcare provider will decide if you should take MYSOLINE while you are pregnant.
  - If you become pregnant while taking MYSOLINE, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) 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 or plan to breastfeed. MYSOLINE can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take MYSOLINE.

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking MYSOLINE with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

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

### **How should I take MYSOLINE?**

Take MYSOLINE exactly as prescribed. Your healthcare provider will tell you how much MYSOLINE to take and when to take it.

- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- Do not stop taking MYSOLINE without first talking to your healthcare provider. Stopping MYSOLINE suddenly can cause serious problems.
- If you take too much MYSOLINE, call your healthcare provider or local Poison Control Center right away.

### **What should I avoid while taking MYSOLINE?**

- MYSOLINE can make you sleepy or dizzy. Do not drink alcohol or take other drugs that make you sleepy or dizzy while taking MYSOLINE without first discussing this with your healthcare provider. Taking MYSOLINE with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how MYSOLINE affects you. MYSOLINE can slow your thinking and motor skills.

### **What are the possible side effects of MYSOLINE?**

See "**What is the most important information I should know about MYSOLINE?**".

MYSOLINE may cause other serious side effects including:

- Sleepiness that can be severe, especially when you first start taking MYSOLINE.
- MYSOLINE may rarely cause blood problems. Symptoms may include:
  - fever, swollen glands, or sore throat that come and go or do not go away
  - Frequent infections or an infection that does not go away
  - tiredness
  - shortness of breath
- MYSOLINE may rarely cause allergic reactions. Symptoms may include:
  - skin rash
  - hives
  - sores in your mouth
  - blistering or peeling skin

The most common side effects of MYSOLINE include:

- problems with walking and moving
- feelings of dizziness, spinning, or swaying (vertigo)

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

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

**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 MYSOLINE?**

Store MYSOLINE at room temperature between 68°F to 77°F (20°C to 25°C) in a tight, light-resistant container

**Keep MYSOLINE and all medicines out of the reach of children.**

#### **General Information about MYSOLINE**

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

This Medication Guide summarizes the most important information about MYSOLINE. If you

would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about MYSOLINE that is written for health professionals.

For more information, go to [www.VALEANT.com](http://www.VALEANT.com) or call 1-877-361-2719

**What are the ingredients in MYSOLINE?**

Active Ingredient: primidone

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, methylcellulose, sodium starch glycolate, sodium lauryl sulfate, magnesium stearate, talc, purified water and Ferric oxide (250 mg tablet only)

**Valeant Pharmaceuticals North America**

**Aliso Viejo, CA 92656**

Issued July 2010

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

Part No. EM 10142/a

Rev. 07/10