

MEDICATION GUIDE

Felbamate (fel bam' ate) Tablets, USP

Read this Medication Guide before you start taking felbamate tablets 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 felbamate tablets?

Do not stop taking felbamate tablets without first talking to your healthcare provider. Stopping felbamate tablets suddenly can cause serious problems.

Felbamate tablets can cause serious side effects, including:

1. Felbamate tablets may cause serious blood problems that may be life-threatening.

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

- Fever, sore throat or other infections that come and go or do not go away
- Frequent infections or an infection that does not go away
- Easy bruising
- Red or purple spots on your body
- Bleeding gums or nose bleeds
- Severe fatigue or weakness

2. Liver problems that may be life-threatening. Call your healthcare provider right away if you have any of these symptoms:

- yellowing of your skin or the whites of your eyes (jaundice)
- dark urine
- nausea or vomiting
- loss of appetite
- pain on the right side of your stomach (abdomen)

3. Like other antiepileptic drugs, felbamate 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
- 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 felbamate tablets without first talking to a healthcare provider.

Stopping felbamate tablets suddenly can cause serious problems. You should talk to your healthcare provider before stopping. Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures.

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 are felbamate tablets?

Felbamate tablets are a prescription medicine used when other treatments have failed in:

- adults alone or with other medicines to treat:
 - partial seizures with and without generalization
- children with other medicines to treat:
 - seizures associated with Lennox-Gastaut syndrome

Who should not take felbamate tablets?

Do not take felbamate tablets if you:

- are allergic to felbamate, carbamates or any of the ingredients in felbamate tablets. See the end of this Medication Guide for a complete list of ingredients in felbamate tablets.
- have or have had blood problems
- have or have had liver problems

What should I tell my healthcare provider before taking felbamate tablets?

Before you take felbamate tablets, tell your healthcare provider if you:

- have kidney problems
- have or have had depression, mood problems, or suicidal thoughts or behavior
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if felbamate tablets can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking felbamate tablets. You and your healthcare provider will decide if you should take felbamate tablets while you are pregnant.
 - If you become pregnant while taking felbamate tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose

of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334.

- are breastfeeding or plan to breastfeed. Felbamate may pass into your breast milk. You and your healthcare provider should decide if you should take felbamate tablets while you breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking felbamate tablets 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 when you get a new medicine.

How should I take felbamate tablets?

- Take felbamate exactly as your healthcare provider tells you. Your healthcare provider will tell you how much felbamate to take and when to take it.
- Your healthcare provider may change your dose of felbamate. Do not change your dose of felbamate without talking to your healthcare provider.
- Because of the risk of serious blood and liver problems, your healthcare provider may do blood tests before you start and while you take felbamate tablets.
- If you take too much felbamate, call your healthcare provider or local Poison Control Center right away.
- Do not stop felbamate tablets without first talking to your healthcare provider.

What should I avoid while taking felbamate tablets?

- Felbamate tablets can cause drowsiness and dizziness. Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking felbamate tablets, until you talk with your doctor. Taking felbamate tablets with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

What are the possible side effects of felbamate tablets?

See “What is the most important information I should know about felbamate tablets?” Felbamate tablets may cause serious side effects including:

The most common side effects of felbamate tablets include:

- weight loss
- vomiting
- trouble sleeping
- nausea
- dizziness
- sleepiness
- headache
- double-vision
- changes in the way that food tastes

These are not all the possible side effects of felbamate tablets. 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 Viona Pharmaceuticals Inc. at 1-888-304-5011 or FDA at 1-800-FDA-1088.

How should I store felbamate tablets?

- Store felbamate tablets between 20°C to 25°C (68°F to 77°F).

Keep felbamate tablets and all medicines out of the reach of children.

General information about felbamate tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use felbamate tablets for a condition for which it was not prescribed. Do not give felbamate tablets 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 felbamate tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about felbamate tablets that is written for health professionals.

What are the ingredients in felbamate tablets?

Active Ingredient: Felbamate, USP

Inactive Ingredients: colloidal silicon dioxide, ferric oxide yellow, FD & C red no. 40 aluminum lake, lactose monohydrate, microcrystalline cellulose, magnesium stearate, povidone K 30, pregelatinised starch (botanical source: corn) and sodium starch glycolate type A (botanical source: potato). Apart from this felbamate tablets USP, 600 mg also contain D & C yellow no. 10 aluminum lake.

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

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