

MEDICATION GUIDE

Peganone® 250 mg Tablets (PEG-ah-noan) (ethotoin tablets, USP)

Read this Medication Guide before you start taking PEGANONE 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 PEGANONE?
Do not stop taking PEGANONE without first talking to your healthcare provider. Stopping PEGANONE suddenly can cause serious problems.

PEGANONE can cause serious side effects, including:

Like other antiepileptic drugs, PEGANONE 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 PEGANONE without first talking to a healthcare provider.

- Stopping PEGANONE 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 PEGANONE?

PEGANONE is a prescription medicine used to treat tonic-clonic (grand mal) and complex partial (psychomotor) seizures.

It is not known if PEGANONE is safe or effective in children younger than 1 year old.

Who should not take PEGANONE?

Do not take PEGANONE if you have:

- liver problems
- blood problems

What should I tell my healthcare provider before taking PEGANONE?

Before you take PEGANONE, 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 plan to become pregnant. PEGANONE may harm your unborn baby and cause birth defects. Birth defects may occur even in children born to women who are not taking any medicines and do not have other risk factors. Tell your healthcare provider right away if you become pregnant while taking PEGANONE. You and your healthcare provider should decide if you will take PEGANONE while you are pregnant
 - If you become pregnant while taking PEGANONE, 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 or plan to breastfeed. PEGANONE can pass into breast milk. You and your healthcare provider should decide if you will take PEGANONE or breast feed. You should not do both. Talk to your healthcare provider about the best way to feed your baby if you take PEGANONE.

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

Taking PEGANONE 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.

Especially tell your healthcare provider if you take medicines that affect blood clotting.

How should I take PEGANONE?

- Take PEGANONE exactly as your healthcare provider tells you. Your healthcare provider will tell you how much PEGANONE to take.
- Your healthcare provider may change your dose. Do not change your dose of PEGANONE without talking to your healthcare provider.
- Do not stop taking PEGANONE without first talking to your healthcare provider. Stopping PEGANONE suddenly can cause serious problems.
- Take PEGANONE after eating, and space doses out evenly.
- If you take too much PEGANONE, call your healthcare provider or local Poison Control Center right away.

What are the possible side effects of PEGANONE?

See “**What is the most important information I should know about PEGANONE?**”.

PEGANONE may cause other rare, but serious side effects. These include:

- **Blood problems** – symptoms may include: not feeling well, sore throat, fever, bruising easily, red or purple spots on your body, nose bleed
- **Liver problems** – symptoms may include: 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, bruising easily.
- **Swollen glands (enlarged lymph nodes)**
- **Lupus** – symptoms may include: a rash on your cheeks or other parts of your body, sensitivity to the sun, new joint or muscle pains, chest pain or shortness of breath, swelling of your feet, ankles, and legs.
- **Serious Rash** – symptoms may include: skin rash, hives, sore throat, sores in your mouth, your skin blisters and peels, swelling of your face, eyes, lips, tongue, or throat.

Call your healthcare provider right away if you have any of the symptoms listed above.

The most common side effects of PEGANONE include:

- nausea or vomiting
- tiredness
- rash
- dizziness
- jerky eye movements
- problems with walking and balance
- double vision
- overgrowth of gum tissue

These are not all the possible side effects of PEGANONE. 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 PEGANONE?

- Store at 20-25°C (68-77°F).
- Keep PEGANONE in a tightly closed container, and keep PEGANONE out of the light.

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

General Information about PEGANONE

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

For more information, go to www.recordatirarediseases.com or call 1-888-575-8344.

What are the ingredients in PEGANONE?

Active ingredient: ethotoin

Inactive ingredients: acacia, lactose, sodium carboxymethylcellulose, stearic acid and talc.

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

Manufactured by: UPM Pharmaceuticals, 501 5th Street, Bristol, TN 37620, U.S.A.

For: Recordati Rare Diseases Inc., Lebanon, NJ 08833, U.S.A.



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