

MEDICATION GUIDE

Phenytoin Oral Suspension, USP

125 mg/5 mL

(FOR ORAL ADMINISTRATION ONLY; NOT FOR PARENTERAL USE)

Rx Only

VP2097R1

VC111074

02/12

Read this Medication Guide before you start taking Phenytoin Oral Suspension, USP 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. If you have any questions about Phenytoin Oral Suspension, USP, ask your healthcare provider or pharmacist.

What is the most important information I should know about Phenytoin Oral Suspension, USP?

Do not stop taking Phenytoin Oral Suspension, USP without first talking to your healthcare provider.

Stopping Phenytoin Oral Suspension, USP suddenly can cause serious problems.

Phenytoin Oral Suspension, USP can cause serious side effects including:

1. Like other antiepileptic drugs, Phenytoin Oral Suspension, USP 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 taking Phenytoin Oral Suspension, USP without first talking to a healthcare provider.

Stopping Phenytoin Oral Suspension, USP 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.

2. Phenytoin Oral Suspension, USP may harm your unborn baby.

- If you take Phenytoin Oral Suspension, USP during pregnancy, your baby is at risk for serious 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
- If you take Phenytoin Oral Suspension, USP during pregnancy, your baby is also at risk for bleeding problems right after birth. Your healthcare provider may give you and your baby medicine to prevent this.
- All women of child-bearing age should talk to their healthcare provider about using other possible treatments instead of Phenytoin Oral Suspension, USP. If the decision is made to use Phenytoin Oral Suspension, USP, you should use effective birth control (contraception) unless you are planning to become pregnant.
- Tell your healthcare provider right away if you become pregnant while taking Phenytoin Oral Suspension, USP. You and your healthcare provider should decide if you will take Phenytoin Oral Suspension, USP while you are pregnant.
- Pregnancy Registry: If you become pregnant while taking Phenytoin Oral Suspension, USP, 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.

3. Swollen glands (lymph nodes)

4. Allergic reactions or serious problems which may affect organs and other parts of your body like the liver or blood cells. You may or may not have a rash with these types of reactions. Symptoms can include any of the following:

- swelling of your face, eyes, lips, or tongue
- trouble swallowing or breathing
- a skin rash
- hives
- fever, swollen glands (lymph nodes), or sore throat that do not go away or come and go
- painful sores in the mouth or around your eyes
- yellowing of your skin or eyes
- bruising or bleeding
- severe fatigue or weakness
- severe muscle pain
- frequent infections or an infection that does not go away
- loss of appetite (anorexia)
- nausea or vomiting

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

What is Phenytoin Oral Suspension, USP?

Phenytoin Oral Suspension, USP is a prescription medicine used to treat tonic-clonic (grand mal), complex partial (psychomotor or temporal lobe) seizures, and to prevent and treat seizures that happen during or after brain surgery.

Who should not take Phenytoin Oral Suspension, USP?

Do not take Phenytoin Oral Suspension, USP if you:

- are allergic to phenytoin or any of the ingredients in Phenytoin Oral Suspension, USP. See the end of this leaflet for a complete list of ingredients in Phenytoin Oral Suspension, USP.
- have had an allergic reaction to CEREBYX (fosphenytoin), PEGANONE (ethotoin), or MESANTOIN (mephenytoin).
- take delavirdine

What should I tell my healthcare provider before taking Phenytoin Oral Suspension, USP?

Before you take Phenytoin Oral Suspension, USP, tell your healthcare provider if you:

- Have or had liver disease

- Have or had porphyria
- Have or had diabetes
- Have or have had depression, mood problems, or suicidal thoughts or behavior
- Are pregnant or plan to become pregnant. If you become pregnant while taking Phenytoin Oral Suspension, USP, the level of Phenytoin Oral Suspension, USP in your blood may decrease, causing your seizures to become worse. Your healthcare provider may change your dose of Phenytoin Oral Suspension, USP.
- Are breast feeding or plan to breastfeed. Phenytoin Oral Suspension, USP can pass into breast milk. You and your healthcare provider should decide if you will take Phenytoin Oral Suspension, USP or breastfeed. You should not do both.

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

Taking Phenytoin Oral Suspension, USP 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 Phenytoin Oral Suspension, USP?

- Take Phenytoin Oral Suspension, USP exactly as prescribed. Your healthcare provider will tell you how much Phenytoin Oral Suspension, USP to take.
- Your healthcare provider may change your dose. Do not change your dose of Phenytoin Oral Suspension, USP without talking to your healthcare provider.
- Phenytoin Oral Suspension, USP can cause overgrowth of your gums. Brushing and flossing your teeth and seeing a dentist regularly while taking Phenytoin Oral Suspension, USP can help prevent this.
- If you take too much Phenytoin Oral Suspension, USP, call your healthcare provider or local Poison Control Center right away.
- Do not stop taking Phenytoin Oral Suspension, USP without first talking to your healthcare provider. Stopping Phenytoin Oral Suspension, USP suddenly can cause serious problems.

What should I avoid while taking Phenytoin Oral Suspension, USP?

Do not drink alcohol while you take Phenytoin Oral Suspension, USP without first talking to your healthcare provider. Drinking alcohol while taking Phenytoin Oral Suspension, USP may change your blood levels of Phenytoin Oral Suspension, USP which can cause serious problems.

Do not drive, operate heavy machinery, or do other dangerous activities until you know how Phenytoin Oral Suspension, USP affects you. Phenytoin Oral Suspension, USP can slow your thinking and motor skills.

What are the possible side effects of Phenytoin Oral Suspension, USP?

See "**What is the most important information I should know about Phenytoin Oral Suspension, USP?**"

Phenytoin Oral Suspension, USP may cause other serious side effects including:

- Softening of your bones (osteopenia, osteoporosis and osteomalacia). This can cause broken bones.

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

The most common side effects of Phenytoin Oral Suspension, USP include:

- problems with walking and coordination
- slurred speech
- confusion
- dizziness
- trouble sleeping
- nervousness
- tremor
- headache

- nausea
- vomiting
- constipation
- rash

These are not all the possible side effects of Phenytoin Oral Suspension, USP. 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 Phenytoin Oral Suspension, USP?

- Store Phenytoin Oral Suspension, USP at controlled room temperature 20°–25°C (68°–77°F) [See USP Controlled Room Temperature]. Preserve in a tight container. Avoid Freezing. Protect from light.

Keep Phenytoin Oral Suspension, USP and all medicines out of the reach of children.

General information about Phenytoin Oral Suspension, USP

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

For more information about Phenytoin Oral Suspension, USP, call VistaPharm Inc., at (727)530-1633.

What are the ingredients in Phenytoin Oral Suspension, USP?

Active ingredient: phenytoin, USP

Inactive ingredients: anhydrous citric acid, USP; carboxymethylcellulose sodium, USP; FD&C Yellow #6; flavor orange-vanilla; glycerin, USP; magnesium aluminum silicate, NF; polysorbate 80, NF; purified water, USP; sodium benzoate, NF and sucrose, NF.

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

SHAKE WELL BEFORE USING

Rx only

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