

# MEDICATION GUIDE

## PHENYTOIN CHEWABLE TABLETS, USP

(fen' i toyn)  
50 mg

Read this Medication Guide before you start taking phenytoin chewable 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. If you have any questions about phenytoin chewable tablets, ask your healthcare provider or pharmacist.

### What is the most important information I should know about phenytoin chewable tablets?

**Do not stop taking phenytoin chewable tablets without first talking to your healthcare provider.**

Stopping phenytoin chewable tablets suddenly can cause serious problems.

**Phenytoin chewable tablets can cause serious side effects including:**

**1. Like other antiepileptic drugs, phenytoin chewable tablets 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 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 chewable tablets without first talking to a healthcare provider.**

- Stopping phenytoin chewable tablets 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 chewable tablets may harm your unborn baby.**

- If you take phenytoin chewable tablets 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 chewable tablets 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 chewable tablets. If the decision is made to use phenytoin chewable tablets, 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 chewable tablets. You and your healthcare provider should decide if you will take phenytoin chewable tablets while you are pregnant.

- **Pregnancy Registry:** If you become pregnant while taking phenytoin chewable tablets, 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 are phenytoin chewable tablets?**

Phenytoin chewable tablets are 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 chewable tablets?**

Do not take phenytoin chewable tablets if you:

- are allergic to phenytoin or any of the ingredients in phenytoin chewable tablets. See the end of this leaflet for a complete list of ingredients in phenytoin chewable tablets.
- 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 chewable tablets?**

Before you take phenytoin chewable tablets, 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 chewable tablets, the level of phenytoin in your blood may decrease, causing your seizures to become worse. Your healthcare provider may change your dose of phenytoin chewable tablets.
- are breast-feeding or plan to breast-feed. Phenytoin can pass into breast milk. You and your healthcare provider should decide if you will take phenytoin chewable tablets or breast-feed. 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 chewable 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 phenytoin chewable tablets?

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

### What should I avoid while taking phenytoin chewable tablets?

Do not drink alcohol while you take phenytoin chewable tablets without first talking to your healthcare provider. Drinking alcohol while taking phenytoin chewable tablets may change your blood levels of phenytoin which can cause serious problems.

Do not drive, operate heavy machinery, or do other dangerous activities until you know how phenytoin chewable tablets affect you. Phenytoin chewable tablets can slow your thinking and motor skills.

### What are the possible side effects of phenytoin chewable tablets?

See "What is the most important information I should know about phenytoin chewable tablets?".

#### Phenytoin chewable tablets 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 chewable tablets 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 chewable 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 FDA at 1-800-FDA-1088.

### How should I store phenytoin chewable tablets?

- Store phenytoin chewable tablets at room temperature between 20° to 25°C (68° to 77°F). Protect from moisture.

#### Keep phenytoin chewable tablets and all medicines out of the reach of children.

### General information about phenytoin chewable tablets

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

For more information about phenytoin chewable tablets, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

### What are the ingredients in phenytoin chewable tablets?

The 50 mg tablets are pink, round, scored tablets debossed with **M** above the

score and **P50** below the score on one side of the tablet and blank on the other side.

Active ingredient: 50 mg phenytoin, USP

Inactive ingredients: colloidal silicon dioxide, compressible sugar, corn starch, D&C Red No. 30 Aluminum Lake, magnesium stearate, peppermint flavor and talc.

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

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MG:PHTA:R3mh



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