MEDICATION GUIDE

PHENYTEK® CAPSULES
(extended phenytoin sodium capsules, USP)
200 mg and 300 mg

Read this Medication Guide before you start taking PHENYTEK® CAPSULES 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 PHENYTEK® CAPSULES, ask your healthcare provider or pharmacist.

What is the most important information I should know about PHENYTEK® CAPSULES?

Do not stop taking PHENYTEK® CAPSULES without first talking to your healthcare provider. Stopping PHENYTEK® CAPSULES suddenly can cause serious problems.

PHENYTEK® CAPSULES can cause serious side effects including:

1. **Like other antiepileptic drugs, PHENYTEK® CAPSULES 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 PHENYTEK® CAPSULES without first talking to a healthcare provider. Stopping PHENYTEK ® CAPSULES 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.

PHENYTEK® CAPSULES may harm your unborn baby.

- If you take PHENYTEK ® CAPSULES 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 PHENYTEK ® CAPSULES 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 PHENYTEK ® CAPSULES. If the decision is made to use PHENYTEK ® CAPSULES, 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 PHENYTEK ® CAPSULES. You and your healthcare provider should decide if you will take PHENYTEK ® CAPSULES while you are pregnant.
- **Pregnancy Registry:** If you become pregnant while taking PHENYTEK ® CAPSULES, 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 PHENYTEK® CAPSULES?

PHENYTEK® CAPSULES 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 PHENYTEK® CAPSULES?

Do not take PHENYTEK® CAPSULES if you:

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

What should I tell my healthcare provider before taking PHENYTEK® CAPSULES?

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

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

What should I avoid while taking PHENYTEK® CAPSULES?

- Do not drink alcohol while you take PHENYTEK ® CAPSULES without first talking to your healthcare provider. Drinking alcohol while taking PHENYTEK ® CAPSULES 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 PHENYTEK ® CAPSULES affect you. PHENYTEK ® CAPSULES can slow your thinking and motor skills.

What are the possible side effects of PHENYTEK® CAPSULES?

See "What is the most important information I should know about PHENYTEK® CAPSULES?"

PHENYTEK® CAPSULES 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 PHENYTEK® CAPSULES 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 PHENYTEK® CAPSULES. 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 PHENYTEK® CAPSULES?

- Store PHENYTEK ® CAPSULES at room temperature between 20° to 25°C (68° to 77°F) in tight, light-resistant containers.
- Protect from light and moisture.

Keep PHENYTEK® CAPSULES and all medicines out of the reach of children.

General information about PHENYTEK® CAPSULES

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

For more information about PHENYTEK® CAPSULES, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

What are the ingredients in PHENYTEK® CAPSULES (extended phenytoin sodium capsules, USP)?

The 200 mg capsule has a dark blue opaque cap and a blue opaque body. The hard-shell gelatin capsule is filled with two white to off-white round tablets. The capsule is rectified radial printed with **BERTEK** over **670** in black ink on both the cap and the body.

The 300 mg capsule has a blue opaque cap and a blue opaque body. The hard-shell gelatin capsule is filled with three white to off-white round tablets. The capsule is rectified radial printed with **BERTEK** over **750** in black ink on both the cap and the body.

Active ingredient: phenytoin sodium, USP

Inactive ingredients: colloidal silicon dioxide, hydroxyethyl cellulose, magnesium oxide, magnesium stearate, microcrystalline cellulose, povidone and sodium lauryl sulfate. In addition, each of the empty gelatin capsules contains the following: FD&C Blue No. 1, gelatin, sodium lauryl sulfate and titanium dioxide. The imprinting ink contains the following: black iron oxide, D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, FD&C Red No. 40 Aluminum Lake, propylene glycol and shellac glaze.

U.S. Patent No. 6,274,168

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

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