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MEDICATION GUIDE

Extended Phenytoin (FEN-i-toyn) Sodium Capsules, USP

What is the most important information I should know about extended phenytoin sodium capsules?

1. Do not stop taking extended phenytoin sodium capsules without first talking to your healthcare provider.

- Stopping extended phenytoin sodium capsules suddenly can cause serious problems.
- Stopping a seizure medicine suddenly can cause you to have seizures more often or seizures that will not stop (status epilepticus).

2. Like other antiepileptic drugs, extended phenytoin sodium 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
- New or worse anxiety
- Trouble sleeping (insomnia)
- Acting on dangerous impulses
- Attempts to commit suicide
- Feeling agitated or restless
- New or worse irritability
- An extreme increase in activity and talking (mania)
- New or worse depression
- Panic attacks

- Acting aggressive, being angry, or violent
- Other unusual changes in behavior or mood

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.

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.

3. Extended phenytoin sodium capsules can cause a type of serious allergic reaction that may affect different parts of the body such as your liver, kidneys, blood, heart, skin or other parts of your body. These can be very serious and cause death. Call your healthcare provider right away if you have any or all of these symptoms:

- Fever
- Sore throat
- Not wanting to eat (anorexia)
- Rash
- Sores in your mouth
- Nausea
- Swollen lymph glands
- Bruise easily
- Vomiting
- Swelling of your face, eye, lips, or tongue
- Purple or red spots on your skin
- Yellowing of the skin and the white part of your eyes (jaundice)
- Trouble swallowing or breathing
- Increase infections

Call your healthcare provider even if the symptoms are mild or if you have been taking extended phenytoin sodium capsules for an extended period of time. These symptoms can be a sign of a serious allergic reaction.

4. Extended phenytoin sodium capsules can cause problems with your heart, including a slow heartbeat. Let your healthcare provider know right away if you have any of these symptoms:

- dizziness
- tiredness
- feeling like your heart is beating slowly or skipping beats
- chest pain

What is extended phenytoin sodium capsule?

Extended phenytoin sodium capsule is a prescription medicine used to treat certain types of seizures called tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures.

Do not take extended phenytoin sodium capsules if you:

- Are allergic to phenytoin or any of the ingredients in extended phenytoin sodium capsules. See the end of this leaflet for a complete list of ingredients in extended phenytoin sodium capsules.
- Have had an allergic reaction to CEREBYX* (fosphenytoin), PEGANONE* (ethotoin), or MESANTOIN* (mephenytoin).
- Have had liver problems from taking phenytoin.
- Take delavirdine.

Before taking extended phenytoin sodium capsules, tell your healthcare provider about all of your medical conditions, including if you:

- Have or have had depression, mood problems, or suicidal thoughts or behavior

- Have had an allergic reaction to a medicine similar to extended phenytoin sodium capsules called carboxamides, barbiturates, succinimides, and oxazolidinediones

- Have or had liver or kidney problems
- Have or had an enzyme problem called porphyria
- Have or had high blood sugar (hyperglycemia)
- Drink alcohol
- Are pregnant or plan to become pregnant. Extended phenytoin sodium capsules may harm your unborn baby.

- If you take extended phenytoin sodium capsules during pregnancy, your baby is at risk for serious birth defects.

- If you become pregnant while taking extended phenytoin sodium capsules, the level of extended phenytoin sodium capsules in your blood may decrease, causing your seizures to become worse. Your healthcare provider may change your dose of extended phenytoin sodium capsules.

- If you take extended phenytoin sodium 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 extended phenytoin sodium capsules.

- If you are of childbearing age and are not planning on getting pregnant, you should use effective birth control (contraception) while taking extended phenytoin sodium capsules.

- Pregnancy Registry:** If you become pregnant while taking extended phenytoin sodium 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.

- Are breastfeeding or plan to breastfeed. Phenytoin sodium can pass into breast milk. You and your healthcare provider should decide if you will take extended phenytoin sodium capsules while you are breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. These medicines can change the levels of phenytoin sodium in your blood.

Taking extended phenytoin sodium 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 extended phenytoin sodium capsules?

- Take extended phenytoin sodium capsules exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how many extended phenytoin sodium capsules to take and when to take it.
- Your healthcare provider may change your dose if needed. Do not change your dose of extended phenytoin sodium capsules without talking to your healthcare provider.

- If your healthcare provider has prescribed phenytoin oral suspension, ask your pharmacist for a medicine dropper or medicine cup to help you measure the correct amount of extended phenytoin sodium capsules. **Do not** use a household teaspoon. Ask your pharmacist for instructions on how to use the measuring device the right way.
- Do not stop taking extended phenytoin sodium capsules without first talking to your healthcare provider. Stopping extended phenytoin sodium capsules suddenly can cause serious problems.

What should I avoid while taking extended phenytoin sodium capsules?

- Do not drink alcohol while you take extended phenytoin sodium capsules without first talking to your healthcare provider. Drinking alcohol while taking extended phenytoin sodium capsules may change your blood levels of phenytoin sodium which can cause serious problems.
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how extended phenytoin sodium capsules affects you. Extended phenytoin sodium capsules can slow your thinking and motor skills.

What are the possible side effects of extended phenytoin sodium capsules?

See "What is the most important information I should know about extended phenytoin sodium capsules?"

Extended phenytoin sodium capsules may cause other serious side effects including:

- Liver problems.
- Low blood count which could increase your chance of getting infections, bruising, bleeding and increased fatigue

- Softening of your bones (osteopenia, osteoporosis, and osteomalacia) can cause your bones to break (fractures).
- High blood sugar (hyperglycemia).
- High levels of extended phenytoin sodium capsules in your blood that could cause confusion also known as delirium, psychosis or a more serious condition that affects how your brain works (encephalopathy).

Call your healthcare provider right away, if you have any of the symptoms listed above. The most common side effects of extended phenytoin sodium capsules include:

- Irregular movement of the eye (nystagmus)
- Slurred speech
- Drowsiness (somnolence)
- Problems with movement and balance (ataxia)
- Decrease in coordination
- Confusion

Extended phenytoin sodium capsules can cause overgrowth of your gums. Brushing and flossing your teeth and seeing a dentist regularly while taking extended phenytoin sodium capsules can help prevent this from happening.

These are not all of the possible side effects of extended phenytoin sodium capsules.

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 extended phenytoin sodium capsules?

- Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).
- Store in tight, light-resistant containers.
- Protect from light and moisture.
- Extended phenytoin sodium capsules come in a child-resistant package.

Keep extended phenytoin sodium capsules and all medicines out of the reach of children.

General information about the safe and effective use of extended phenytoin sodium capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use extended phenytoin sodium capsules for a condition for which it was not prescribed. Do not give extended phenytoin sodium capsules to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about extended phenytoin sodium capsules that is written for health professionals.

What are the ingredients in extended phenytoin sodium capsules?

Extended phenytoin sodium capsules 200 mg and 300 mg:

Active ingredient: phenytoin sodium
Inactive ingredients: lactitol monohydrate, sodium lauryl sulfate, talc and magnesium stearate. The capsule shell contains gelatin, FD&C Blue # 1, FD&C Red # 40, D&C Red # 28 (200 mg) and FD&C Red # 3 (200 mg) and black printing ink, which contains black iron oxide, shellac, dehydrated alcohol, butyl alcohol, propylene glycol, strong ammonia solution, and potassium hydroxide.

For more information call at 1-800-818-4555.

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