DILANTIN- phenytoin sodium capsule, extended release
Parke-Davis Div of Pfizer Inc

MEDICATION GUIDE

DILANTIN (Dī lan' tĭn)
(Phenytoin and Phenytoin sodium)

Oral Suspension, Tablets, Extended Oral Capsules

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

What is the most important information I should know about DILANTIN?

Do not stop taking DILANTIN without first talking to your healthcare provider.

Stopping DILANTIN suddenly can cause serious problems.

DILANTIN can cause serious side effects including:

1. **Like other antiepileptic drugs, DILANTIN 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 DILANTIN without first talking to a healthcare provider.

- Stopping DILANTIN 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. **Dilantin may harm your unborn baby.**
   - If you take DILANTIN 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 DILANTIN 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 DILANTIN. If the decision is made to use DILANTIN, 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 DILANTIN. You and your healthcare provider should decide if you will take DILANTIN while you are pregnant.
   - Pregnancy Registry: If you become pregnant while taking DILANTIN, 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 include:
   - swelling of your face, eyes, lips, or tongue
   - trouble swallowing or breathing

- a skin rash
- hives
- fever, swollen glands, 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
- unusual bruising or bleeding
- severe fatigue or weakness
- severe muscle pain
- frequent infections or an infection that does not go away

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

What is DILANTIN?

DILANTIN 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 DILANTIN?

Do not take DILANTIN if you:

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

What should I tell my healthcare provider before taking DILANTIN?

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

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

What should I avoid while taking DILANTIN?

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

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

What are the possible side effects of DILANTIN?

See "**What is the most important information I should know about DILANTIN?**"

DILANTIN may cause other serious side effects including:

- Softening of your bones (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 DILANTIN 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 DILANTIN. 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 DILANTIN?

- Store DILANTIN-125 Suspension at room temperature between 68°F to 77°F (20°C to 25°C). Protect from light. Do not freeze.
- Store DILANTIN INFATABS at room temperature between 68°F to 77°F (20°C to 25°C). Protect from moisture.
- Store DILANTIN Capsules at room temperature between 68°F to 77°F (20°C to 25°C) in tight, light-resistant containers. Protect from moisture.

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

General information about DILANTIN

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

For more information about DILANTIN, visit http://www.pfizer.com or call 1-800-438-1985.

What are the ingredients in DILANTIN?

Oral Suspension

Active ingredient: phenytoin

Inactive ingredients: USP; alcohol, USP (maximum content not greater than 0.6 percent); banana flavor; carboxymethylcellulose sodium, USP; citric acid, anhydrous, USP; glycerin, USP; magnesium aluminum silicate, NF; orange oil concentrate; polysorbate 40, NF; purified water, USP; sodium benzoate, NF; sucrose, NF; vanillin, NF; and FD&C yellow No. 6.

Tablet

Each tablet is a yellow triangular scored chewable tablet.

Active ingredient: 50 mg phenytoin

Inactive ingredients: D & C yellow No. 10, A1 lake, FD&C yellow No. 6, flavor, saccharin sodium, sucrose, talc, and other ingredients.

Extended Oral Capsule

Dilantin 100mg: Each capsule contains a white powder. The medium orange cap has "PD" imprinted in black ink and the white, opaque body has "DILANTIN" over "100 mg" printed in black ink.

Active ingredient: 100 mg phenytoin sodium

Inactive ingredients: lactose monohydrate, confectioner's sugar, talc, and magnesium stearate. The capsule body contains titanium dioxide and gelatin. The capsule cap contains FD&C red No. 28, FD&C yellow No. 6, and gelatin.

Dilantin 30mg: Each capsule contains a white powder. The small pale pink opaque cap has "PD" imprinted in black ink and the white, opaque body has "Dilantin 30 mg" printed in black ink.

Active ingredient: 30 mg phenytoin sodium

Inactive ingredients: lactose monohydrate, confectioner's sugar, talc, and magnesium stearate. The capsule shell cap and body contain Titanium Dioxide (cap and body); gelatin (cap and body); D&C yellow No. 10 (cap); FD&C red No. 3 (cap).

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

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