MEDICATION GUIDE
DILANTIN (Di lan' tin)
(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, angry, or violent
   - acting on dangerous impulses
   - an extreme increase activity and talking (mania)
   - other unusual changes in behavior or mood

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.

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:

   - are allergic to phenytoin or any of the ingredients in DILANTIN.
   - have had an allergic reaction to CEREBRYX (tosphenytoin), 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 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 telling 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?

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?

The most common side effects of DILANTIN include:

   - 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
   - blurred speech
   - confusion
   - dizziness
   - trouble sleeping
   - nervousness

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 at room temperature between 60°F to 77°F (20°C to 25°C). Protect from light. Do not freeze.

Store DILANTIN INFATABS at room temperature between 59°F to 86°F (15°C to 30°C).

Store DILANTIN Capsules at room temperature between 88°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?

Dilantin 100mg: 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” over “100 mg” printed in black ink. Active ingredient: 100 mg phenytoin sodium Inactive ingredients: lactose monohydrate, cornstarch, magnesium stearate, sodium starch glycolate, starch, and magnesium stearate. The capsule body contains titanium dioxide and gelatin. The capsule cap contains FD&C red No. 30, 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, cornstarch, sodium starch glycolate, fast blue, and gelatin (cap and body); gelatin (cap and body); FD&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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