

CONSUMER INFORMATION

DILANTIN* INFATABS*

(Phenytoin Tablets USP)

DILANTIN*-30 SUSPENSION /DILANTIN*-125 SUSPENSION

(Phenytoin Oral Suspension USP)

Anticonvulsant

Information for the patient:

Please read this information carefully before you start to take your medicine, even if you have taken this drug before. Do not throw away this leaflet until you have finished your medicine as you may need to read it again. For further information or advice, please ask your doctor or pharmacist.

ABOUT THIS MEDICATION

What the medication is used for:

DILANTIN has been prescribed to you by our doctor to control seizures.

It is specifically used for:

§ the control of generalized tonic-clonic seizures, and psychomotor seizures.

What it does:

DILANTIN Infatabs and DILANTIN-30 Suspension/DILANTIN-125 Suspension belong to the family of medicines called anticonvulsant. It acts in the brain to block the spread of seizure activity.

When it should not be used:

If you are allergic to phenytoin, to other medicines of the hydantoin family, or to any of the nonmedicinal ingredients in the formulations (see **What the nonmedicinal ingredients are**).

What the medicinal ingredient is:

Phenytoin..

What the nonmedicinal ingredients are:

DILANTIN Infatab; alcohol, magnesium stearate spearmint oil, talc and sugar.

DILANTIN-30 and 125 Suspensions: alcohol, banana oil, citric acid, glycerin, magnesium aluminium silicate, orange oil, polysorbate 40, Red #2 FD&C (30 mg/5mL suspension only), sodium benzoate, sodium carboxymethylcellulose sugar, vanillin, yellow #6 FD&C and water.

What dosage forms it comes in:

DILANTIN Infatab: 50 mg phenytoin tablet (free acid form).

DILANTIN-30 Suspension: Each 5 mL of flavoured, red suspension contains 30 mg phenytoin (free acid form).

DILANTIN-125 Suspension: Each 5 mL of flavoured, orange suspension contains 125 mg phenytoin (free acid form).

DILANTIN is also available as extended phenytoin sodium 30 mg and 100 mg capsules.

WARNINGS AND PRECAUTIONS

Do not stop your treatment with DILANTIN without first checking with your doctor as that could cause sudden worsening of your seizure. If you/your child are experiencing any side effects please see “Side Effects and What To Do About Them” section for guidance.

BEFORE you use these medicines, tell your doctor if:

- \$ You/your child are diabetic,
- \$ You/your child are anemic.
- \$ You/your child have low bone density,
- \$ You/your child have or have had any liver disease or blood disorders (including porphyria),
- \$ You/your child have had an allergy to this drug, or other drugs used to treat your condition,
- \$ You are pregnant or thinking about becoming pregnant, or if you are breast-feeding.
- \$ You/your child are taking other drugs (prescription and over-the-counter medicines)
- \$ You consume alcohol on a regular or occasional basis.
- \$ Certain individuals of Asian and /or of black origin may be at an increased risk of developing serious skin reactions during treatment with DILANTIN.
- \$ You/your child have experienced in the past or have a family history of anticonvulsant hypersensitivity syndrome (which may occur rarely in patients treated with anticonvulsant medications and includes symptoms such as fever, rash, hepatitis (such as yellowing of skin and eyes) and lymph node swelling among others).
- \$ You/your child are currently being treated with cranial irradiation and corticosteroids.
- \$ You/your child suffer from absence seizures (petit mal) or seizures caused by low blood sugar (hypoglycemia) or other metabolic causes, as DILANTIN is not effective in controlling these types of seizures.

When taking DILANTIN:

Tell your doctor if you develop serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling and accompanied by fever, tell your doctor immediately. These reactions may be more frequent in patients of Asian origin. Reports of these reactions have been highest in patients from Taiwan, Malaysia and the Philippines. Talk to your doctor about the best way to care for your teeth, gums, and mouth during your treatment with DILANTIN. It is very important that you care for your mouth properly to decrease the risk of gum damage.

INTERACTIONS WITH THIS MEDICATION

There are many drugs that may increase or decrease phenytoin levels, or that DILANTIN may affect, tell your doctor or pharmacist about all other prescription and non-prescriptions medication you are taking, as well as dietary supplements, enteral feeding preparations or nutritional drinks, as there may be a need to adjust your medication or monitor you more carefully.

PROPER USE OF THIS MEDICATION

It is very important that you take these medicines exactly as your doctor has instructed. Never increase or decrease the dose yourself. Do not stop taking it abruptly unless directed by your doctor as your seizures may increase. Tell your doctor if you cannot take the drug as prescribed, for example if you will be having surgery. You should always check that you have an adequate supply of DILANTIN.

Dilantin Infatabs and oral suspension are not for once-a-day dosing. These medications must be taken 2 or 3 times per day.

Dilantin is also available as Extended Phenytoin Sodium Capsules which can be taken once daily. Dosage adjustments are required when switching from Dilantin Infatabs/oral suspension to the extended phenytoin sodium capsules.

Usual dose: The dose is adjusted to suit your/your child response to treatment. In some cases, blood level assessment may be necessary to adjust the dose optimally.

DILANTIN Infatabs

Adult: *Starting dose:* 2 Infatabs 3 times daily.

Maintenance dose: 8 to 12 Infatabs daily.

Pediatric: **Starting dose:** 5 mg/kg/day in 2 or 3 equally divided doses.

Maintenance dose: 4 to 8 mg/kg in 2 or 3 divided doses.

DILANTIN-30 Suspension and DILANTIN-125 Suspension

It is important to use an accurate measuring device when using the oral suspension formulation.

Adult: **Starting dose:** 1 teaspoonful (5 mL) DILANTIN -125 Suspension 3 times daily.

Maintenance dose: Up to 5 teaspoonfuls (25 mL) DILANTIN -125 Suspension daily.

Pediatric: **Starting dose:** 5 mg/kg/day, of DILANTIN Infatabs, DILANTIN-30 Suspension or DILANTIN-125 Suspension in 2 or 3 equally divided doses.

Maintenance dose: 4 to 8 mg/kg/day.

The maximum dose recommended for children is 300 mg/day. Children over 6 years old may require the minimum adult dose (300 mg/day).

If the daily dosage cannot be divided equally, the larger dose should be given at bedtime.

In case of a drug overdose, immediately go to the nearest emergency room even if you/your child do not feel sick. Make sure you take your medicine bottle with you to show the doctor.

Overdose:

Very high doses can cause toxicity or death.

Missed dose:

If you/your child miss/misses a dose, take it as soon as you remember. But if it is almost time for the next dose, do not take the missed dose. Instead, take the next scheduled dose. Do not try to make up for the missed dose by taking a double dose next time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, DILANTIN Infatabs and DILANTIN-30 Suspension/ DILANTIN-125 Suspension can cause side effects, although not everybody gets them.

Serious Side Effects:

- If an allergic or hypersensitivity reaction happens such as fever with lymph nodes swelling, hepatitis (such as jaundice , yellowing of skin and eyes), flu-like symptoms with skin rash or skin blistering, you should go to the emergency department at your nearest hospital right away.
- If you notice symptoms suggestive of hepatitis, such as jaundice (yellowing of skin and eyes), tell your doctor right away.

Other Side Effects:

If you experience any side effects such as unusual eye movement, changes in muscle movements or co-ordination, slurred speech, confusion, dizziness, insomnia, lymph node swelling, changes to facial skin or gums, headache, nausea or vomiting, consult your doctor.

This is not a complete list of side effects. For any unexpected effects, or effects that worry you while taking DILANTIN Infatabs or DILANTIN-30 Suspension/ DILANTIN-125 Suspension, contact your doctor or pharmacist.

HOW TO STORE IT

DILANTIN Infatabs: Store at controlled room temperature 15-30°C. Protect from light and moisture.
DILANTIN-30 Suspension and DILANTIN-125 Suspension: Store at controlled room temperature 15 - 30°C. Protect from freezing and light.
Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

-
- \$ Report online at www.healthcanada.gc.ca/medeffect
- \$ Call toll-free at 1-866-234-2345
- \$ Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.Pfizer.ca>
or by contacting the sponsor, Pfizer Canada, at:
1-800-463-6001

This leaflet was prepared by Pfizer Canada Inc.
17,300 Trans-Canada Highway, Kirkland, Quebec H9J 2M5

Last revised: July 27, 2010