PART III: CONSUMER INFORMATION

DILANTIN® INFATABS®
Phenytoin Tablets USP

DILANTIN®-30 SUSPENSION /DILANTIN®-125 SUSPENSION
Phenytoin Oral Suspension USP

This leaflet is part III of a three-part "Product Monograph" published when DILANTIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DILANTIN.

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. Contact your doctor or pharmacist if you have any questions about the drug.

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 or other medicines of the hydantoin family, including fosphenytoin (CEREBRYX), or to any of the nonmedicinal ingredients in the formulations (see what the nonmedicinal ingredients are).
- If you take Delavirdine (drug used to treat HIV infection).
- If you have slow heart rate (bradycardia), heart block, or other heart problems.

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 DILANTIN talk to your doctor or pharmacist 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 kidney or 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/your child have slow heart rate (bradycardia), fast heart rate (tachycardia), heart block, or a history of cardiac arrest (asystole). Regardless of your cardiac history, tell your doctor if you experience any of the adverse events listed above when taking DILANTIN,
- You are pregnant or thinking about becoming pregnant. If you take DILANTIN during pregnancy your baby is at risk for serious birth defects, such as cleft lip or cleft palate. Birth defects may happen even in children born to women who are not taking any medicines and do not have any other risk factors. All women of child-bearing age who are being treated for epilepsy should talk to their healthcare providers 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. You should talk to your doctor about the best kind of birth control to use while you are taking DILANTIN.
- You are breast-feeding.
- You/your child are taking other drugs (prescription and over-the-counter medicines), dietary or herbal supplements.
- 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. This 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 other symptoms.

- 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.
- You/your child have or have had depression, mood problems, or suicidal thoughts or behavior.

When taking DILANTIN:

- Always take DILANTIN as your doctor has prescribed. If it is not possible for you to take DILANTIN as prescribed, tell your doctor.
- Tell your doctor if you develop a skin rash while taking DILANTIN.
- Tell your doctor right away if you develop serious skin reactions such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling that may be accompanied by fever. 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.
- Tell your doctor if you become pregnant while taking DILANTIN. You and your doctor should decide if you will continue to take DILANTIN while you are pregnant. If you become pregnant while taking DILANTIN, talk to your doctor 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 medicines during pregnancy. Information about the registry can also be found at the website: http://www.aedpregnancyregistry.org/.
- 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.
- It is recommended that you **do not** drink alcohol while taking DILANTIN, without first talking to your doctor. 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.

INTERACTIONS WITH THIS MEDICATION

There are many drugs that may increase or decrease phenytoin levels. DILANTIN may affect the levels of many drugs. Therefore, tell your doctor or pharmacist about all other prescription and non-prescriptions medication you are talking, as well as dietary and herbal 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 prescribed. 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's 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.

Overdose:

Very high doses can cause toxicity or death.

In case of drug overdose, contact the regional Poison Control Centre and talk to a health care practitioner right away, or go to a hospital emergency department even if there are no symptoms. Take your medicine bottle with you to show the doctor.

Missed Dose:
If you/your child miss/misses a dose, take it as soon as you remember. 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Get immediate medical help
		Only if severe	In all cases	
Uncommon	Severe skin reactions (rashes, eruptions, skin blistering)			√
	Skin rash and fever with swollen glands, particularly in the first two months of therapy			√
	Sudden wheeziness, difficulty breathing, swelling of eyelids, face or lips, rash or itching			√
	Bruising, fever, looking pale or severe sore throat		√	
	Seizures or fits		√	√
	Suicidal thoughts, self injury, confusion or disorientation		√	
	Gum disorders (red or bleeding gums)		√	
	Liver failure or disorders (jaundice, yellowing of skin and eyes)		√	√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Get immediate medical
Unknown	Softening of the bones (bone pain, broken bones)		√	

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, vertigo, trouble sleeping (insomnia), lymph node swelling, changes to facial skin or gums, rash, 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** https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html
- **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 1908C
    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 https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

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

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