

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDILANTIN® INFATABS

Phenytoin Chewable Tablets

PrDILANTIN®-30 SUSPENSION

PrDILANTIN®-125 SUSPENSION

Phenytoin Oral Suspension

Read this carefully before you start taking **DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION**.

What are DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION used for?

DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION are used to help:

- control certain types of seizures, called tonic-clonic (grand mal) seizures, and psychomotor (temporal lobe) seizures.

How do DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION work?

DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION belong to a group of medicines called anti-seizure medicines. It works by slowing down electrical impulses in the brain that cause seizures.

What are the ingredients in DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION?

Medicinal ingredients: Phenytoin.

Non-medicinal ingredients:

- **DILANTIN INFATABS:** alcohol, magnesium stearate, spearmint oil, sugar and talc.
- **DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION:** alcohol, banana oil, citric acid, glycerin, magnesium aluminium silicate, orange oil, polysorbate 40, sodium benzoate, sodium carboxymethylcellulose, sugar, vanillin, yellow #6 FD&C and water. DILANTIN-30 SUSPENSION also contains Red #2 FD&C.

DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION come in the following dosage forms:

- **DILANTIN INFATABS:** chewable tablets; 50 mg

- **DILANTIN-30 SUSPENSION:** oral suspension; 30 mg / 5 mL
- **DILANTIN-125 SUSPENSION:** oral suspension; 125 mg / 5 mL

DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION are also available as capsules.

Do not use DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION if you/your child:

- are allergic to phenytoin or any other ingredients in DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION.
- are allergic to other medicines of the hydantoin family, including fosphenytoin.
- take delavirdine (used to treat HIV infection).
- have a heart rhythm condition, such as slow heart rate (bradycardia), heart block, or certain other heart conditions.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you/your child take DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION. Talk about any health conditions or problems you/your child may have, including if you/your child:

- are taking any other medications, supplements or other special treatments.
 - they may interact with DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION, and this can change how well they or DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION work.
 - they include prescription or non-prescription medications, dietary supplements (e.g., vitamins), herbal supplements, nutritional drinks, and enteral feeding preparations.
- have ever had an allergic rash while taking phenytoin or any other anti-seizure medicine.
- have a personal or family history of severe allergic reaction to phenytoin or any other anti-seizure medicines.
 - symptoms can include fever, rash, swollen lymph gland, and liver problems (seen as yellowing of skin and the whites of the eyes)
- drink alcohol occasionally or regularly.
- are 65 years of age or older.
- are female and:
 - are breastfeeding or plan to breastfeed.
 - are pregnant or plan to become pregnant.
 - are using hormonal birth control, such as the birth control pill.
- are of Asian and/or Black descent. You or your child may be at a higher risk of developing serious skin reactions during treatment with DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION.
- have or have had any of the following diseases or conditions:
 - depression, mood problems, or suicidal thoughts or behaviours.
 - diabetes.
 - heart problems, including slow or fast heart rate, or past heart attack.
 - liver or kidney problems.

- low levels of albumin or high levels of bilirubin in the blood.
- porphyria (a condition that affects the nervous system and skin). DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION can worsen your condition.
- immune system problems, such as immune suppression or compromise.
- are having radiation therapy for the brain and take corticosteroids (medicines used to treat inflammation).
- a medical condition (such as surgery) that prevents you from taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION orally.

Other warnings you should know about:

Do not stop your treatment with DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION without first checking with your healthcare professional. This could lead to a sudden worsening of your seizures.

Pregnancy, birth control and breastfeeding:

- Avoid becoming pregnant while you are on DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION. If you become pregnant while taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION, your seizures may become worse. Your healthcare professional may change your dose of DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION.
- If you take DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION during pregnancy, your baby is at risk for serious birth defects, and cognitive disabilities. Your baby is also at risk for bleeding problems right after birth.
- If you are pregnant or able to get pregnant, talk to your healthcare professional about using other treatments instead of DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION. If the decision is made to use DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION, you should use effective birth control (contraception) during your treatment. If you are using hormonal birth control, it might not work with DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION. Talk to your healthcare professional about the best kind of birth control to use while you are taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION.
- Tell your healthcare professional right away if you become pregnant or think you are pregnant during treatment with DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION. You and your healthcare professional should decide if you will continue to take DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION while you are pregnant.
- **Pregnancy Registry:** If you become pregnant while taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION, talk to your healthcare professional 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/>.

- DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION passes into breast milk and may harm your baby. Do not breastfeed during treatment with DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION. Talk to your healthcare professional about the best way to feed your baby during this time.

Driving or using machines: DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION may make you feel dizzy, drowsy and affect your coordination. Avoid driving, using machinery, or doing activities that requires you to be alert until you know how DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION affect you.

Alcohol: Do not drink alcohol while taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION without first talking to your healthcare professional. Drinking alcohol while taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION may change your blood levels of phenytoin, which can cause serious side effects.

Check-ups and testing:

- Your healthcare professional may ask you to do a genetic test before you take DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION. This test will determine if you have a high risk of experiencing serious skin reactions if you are given DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION.
- You will have regular visits with your healthcare professional while you are taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION to monitor your health. They will:
 - do blood tests to monitor the amount of phenytoin in the body.
 - do scans to check your bone health.
 - talk to you about how you are feeling, and if you have suicidal thoughts and behaviours.
- DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION can cause serious side effects, including:

- **Suicidal thoughts and behaviour changes:** This medicine may cause some people to be agitated, irritable, or display other unusual behaviours. It may also cause some people to have suicidal thoughts and tendencies or to become more depressed. You may find it helpful to tell a relative or close friend you are taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION. Ask them to read this leaflet. You might ask them to tell you if they:
 - think your depression is getting worse, or
 - are worried about changes in your behaviour.

If you have thoughts of harming or killing yourself or others at any time, tell your healthcare professional or go to a hospital **right away**. Close observation by a healthcare professional is necessary in this situation.

- **Serious skin reactions:** Serious allergic reactions can be caused by anti-seizure medicines, often involving a skin reaction. These may occur shortly after starting treatment, or several months later. Get help **right away** if you/your child develop a skin rash, regardless of its severity, either alone or with a combination of the following symptoms:
 - any other serious skin reaction such as blistering or peeling of the mouth, nose, eyes or genitals,
 - fever,
 - swollen glands,
 - flu-like feeling,
 - swelling of the face and/or legs,
 - problems related to the liver, kidneys, heart, lungs or other organs.
- **Bone problems (including osteoporosis, osteopenia, osteomalacia):** If you have taken anti-seizure medicines for a long time, it can lead to bone problems. This includes painful and weakened or brittle bones, and possibly bone fractures.
- **Gingival hyperplasia** (overgrowth of gum tissue around the teeth): Talk to your healthcare professional about the best way to care for your teeth, gums, and mouth during your treatment with DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION. It is very important that you care for your mouth properly to decrease the risk of gum damage.

See the **Serious side effects and what to do about them** table for more information on these and other serious side effects.

Tell your healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION may interact with a number of other medicines. Your healthcare professional will monitor you while you are taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION to ensure you are taking the dose that is right for you.

DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION must not be taken with delavirdine, used to treat HIV infection.

The following may interact with DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION:

- medicines used to treat or prevent:
 - seizures or epilepsy (other than DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION)

- bacterial, fungal and parasitic infections
- HIV infection
- cancer
- high blood pressure or certain heart conditions
- high blood cholesterol
- high blood sugar
- blood clots (anticoagulants)
- depression and other psychological conditions
- anxiety or alcohol withdrawal
- pain and inflammation
- excess stomach acid or ulcers,
- medicines used to suppress your immune system, and
- medicines used as a muscle relaxant for intubation or surgery
- these medicines:
 - birth control pills and other birth control methods that use hormones
 - theophylline, used to treat asthma or other breathing problems
 - furosemide, used to lower extra fluid levels
 - halothane, used for general anesthesia
 - methadone, used to treat pain and opioid dependence
 - corticosteroids, used to treat inflammation
 - diazoxide, used to treat low blood sugar
- other supplements:
 - St. John’s Wort, a herbal remedy
 - vitamin D, vitamin B9 (folic acid)
 - tube feeding preparations and related nutritional drinks or supplements
- alcohol.

This is not a complete list.

How to take DILANTIN INFATABS, DILANTIN-30 SUSPENSION, and DILANTIN-125 SUSPENSION:

- Always take DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION exactly as your healthcare professional has told you to. They will decide on the dose that is right for you/your child. Never increase or decrease your dose without talking to your healthcare professional.
- Do not stop taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION without talking to your healthcare professional. Stopping DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION suddenly can cause serious problems, including seizures that will not stop. Your healthcare professional will tell you if and when you/your child can stop taking this medicine.
- DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION should not be taken once a day. It should be taken in 2 or more equally divided doses a day.

Usual dose:

DILANTIN INFATABS

Adults:

- **Usual initial dose:** 300 mg a day, divided into 3 doses (two 50 mg chewable tablets, three times a day). Your dose may be adjusted according to the effect it has, and to the level of medicine in your blood.
- **Usual dose:** 400 - 600 mg total a day, in divided doses. Your healthcare professional may adjust your dose if necessary.

Children (below 18 years of age)

- Your child's healthcare professional will determine the right dose based on your child's weight. Follow their instructions carefully.
- **Usual initial dose:** A total of 5 mg/kg/day (5 mg per day for every kg they weigh), to be divided and given in 2 or 3 equal doses. Your child's dose may be adjusted according to the effect it has, and to the level of medicine in their blood. The maximum dose is 300 mg (total) a day.
- **Usual dose:** 4 to 8 mg/kg/day, in divided doses. 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.

DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION

Adults:

- **Usual initial dose:** 5 mL of DILANTIN-125 SUSPENSION, three times a day. Your dose may be adjusted according to the effect it has, and to the level of medicine in your blood.
- **Usual dose:** 25 mL of DILANTIN-125 SUSPENSION in divided doses. Your healthcare professional may adjust your dose if necessary.

Children (below 18 years of age)

- Your child's healthcare professional will determine the right dose based on your child's weight. Follow their instructions carefully.
- **Usual initial dose:** A total of 5 mg/kg/day (5 mg per day for every kg they weigh), to be divided and given in 2 or 3 equal doses. Your child's dose may be adjusted according to the effect it has, and to the level of medicine in their blood. The maximum dose is 300 mg (total) a day.
- **Usual dose:** 4 to 8 mg/kg/day, in divided doses. 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:

Signs of an overdose with DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION include:

- blurred vision, involuntary eye movements (side-to-side, up and down, circular motion),
- lack of muscle control or coordination, shaking (tremors), overactive reflexes,
- low blood pressure, slow heart rate, poor blood circulation, heart suddenly stops beating (cardiac arrest),
- feeling sleepy or tired, lack of energy,
- slurred or slow speech,
- nausea or vomiting,
- slow and ineffective breathing,
- coma.

If you think you, or a person you are caring for, have taken too much DILANTIN INFATABS, DILANTIN-30 SUSPENSION or DILANTIN-125 SUSPENSION, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child miss a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and take your next dose as scheduled. Do not take a double dose to make up for the missed dose.

What are possible side effects from using DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION?

These are not all the possible side effects you may have when taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- high blood sugar. If you have diabetes, closely monitor your blood sugar while taking DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION.
- spinning or dizziness (vertigo)
- trouble falling asleep, or feeling sleepy
- nausea or vomiting, constipation
- nervousness
- headache
- burning or prickling sensation on the skin (sometimes called “pins and needles”)
- changes in facial features
- additional body and facial hair
- change in tastes

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
COMMON			
Gingival hyperplasia (overgrowth of gum tissue around the teeth): tender gums, inflammation, pain, bad breath, plaque buildup on teeth, gums covering the teeth		✓	
Nervous system problems: may include unusual eye movements, slurred speech, decreased coordination, feeling confused.		✓	
UNCOMMON			
Anemias (problems with the blood and immune system): bruising, fever, looking pale, severe sore throat, tiredness, lack of energy, decreased exercise tolerance		✓	
Angioedema and severe allergic reactions: symptoms may include swelling of the face, eyes, lips or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing, unconsciousness.			✓
Liver problems (including hepatitis, liver failure or damage): yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness, loss of appetite (anorexia)			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Mental changes: feeling confused or disoriented (delirium), seeing, hearing or believing things that aren't real (psychosis).		✓	
Seizures (fits): uncontrollable shaking		✓	
Serious skin reactions: any combination of fever, severe rash, swollen lymph glands. May involve flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, swelling of face and/or legs. May also involve problems related to the liver, kidneys, heart, lungs or other organs.			✓
Skin reactions (rashes, eruptions, skin blistering)			✓
Suicidal thoughts or behaviour changes: unusual behaviours, depression, worsening of depression, leading to thoughts of self-harm or suicide			✓
UNKNOWN FREQUENCY			
Bone problems (including osteoporosis, osteopenia, osteomalacia): bone pain, muscle weakness, difficulty walking, bone fractures		✓	
Heart problems: unusual heart rate (slow, fast or irregular), dizziness, tiredness, shortness of breath, chest pain			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad

enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

DILANTIN INFATABS: Store between 15 - 30°C. Protect from light and moisture.

DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION: Store between 15 - 30°C. Protect from freezing and light.

Keep DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION out of reach and sight of children.

If you want more information about DILANTIN INFATABS, DILANTIN-30 SUSPENSION and DILANTIN-125 SUSPENSION:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.viatris.ca>, or by calling 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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