

# DILANTIN ORAL SUSPENSION

Phenytoin (125 mg/5 mL)

## What is in this leaflet

1. What DILANTIN ORAL SUSPENSION is used for
2. How DILANTIN ORAL SUSPENSION works
3. Before you use DILANTIN ORAL SUSPENSION
4. How to use DILANTIN ORAL SUSPENSION
5. While you are using it
6. Side Effects
7. Storage and Disposal of DILANTIN ORAL SUSPENSION
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

## What DILANTIN ORAL SUSPENSION is used for

DILANTIN ORAL SUSPENSION is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

## How DILANTIN ORAL SUSPENSION works

DILANTIN ORAL SUSPENSION belongs to a group of medicines called anticonvulsants. These drugs are thought to work by controlling brain chemicals, which send signals to nerves so that seizures do not happen.

## Before you use DILANTIN ORAL SUSPENSION

### - When you must not use it

Do not take DILANTIN ORAL SUSPENSION:

- if you have a history of allergy to Phenytoin or to the inactive ingredients of DILANTIN ORAL SUSPENSION or other hydantoin medicines.
- Allergic reactions include a condition called angioedema which causes:

- swelling of the area beneath the skin or mucosa
- if you have a history of liver injury caused by phenytoin
- if you are taking delavirdine (used in the treatment of HIV infection).

### *Pregnancy and lactation*

DILANTIN ORAL SUSPENSION crosses the placenta and may affect your developing baby if you take it during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take DILANTIN ORAL SUSPENSION, your doctor can help you decide whether or not to take it during pregnancy.

Your doctor may ask you

- to get serum phenytoin levels checked.
- to take vitamin K before delivery and give vitamin K to the new born after birth.

Tell your doctor if you are breastfeeding or intend to breastfeed. It is not recommended to breastfeed while taking DILANTIN ORAL SUSPENSION, as it may pass through breast milk and affect your baby.

### - Before you start to use it

Tell your doctor if you have or have had any medical conditions, especially the following:

- liver, heart or kidney problems
- porphyria (a rare blood pigment disorder)
- diabetes
- lymphadenopathy, a condition of the lymph glands
- hypersensitivity syndrome, which results in fever, rash, blood disorders and hepatitis
- low levels of albumin in blood
- a severe skin disorder called Stevens-Johnson syndrome
- toxic epidermal necrolysis, a

severe skin reaction with painful red areas, which cause blister and peel.

There have been reports of bone disorders, including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on a long-term antiepileptic medication or have a history of osteoporosis.

### - Taking other medicines

Tell your doctor if you are taking

- Medicines used for heart and circulation problems (digoxin, amiodarone, quinidine, mexiletine, reserpine, warfarin, ticlopidine, and calcium channel blockers, e.g. nimodipine, nisoldipine, verapamil and nifedipine).
- Other medicines used for epilepsy (ethosuximide, methsuximide, carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine, phenobarbital, sodium valproate and valproic acid, succinimides, vigabatrin, quetiapine).
- Medicines used to treat fungal infections (azoles, such as fluconazole, itraconazole, ketoconazole, miconazole, posaconazole and voriconazole).
- Medicines used for tuberculosis and other bacterial infections (chloramphenicol, isoniazid, rifampin, doxycycline, sulfonamides, such as sulfadiazine, sulfamethizole, sulfamethoxazole – trimethoprim and sulfaphenazole).
- Medicines used for stomach ulcers (omeprazole, sucralfate, the medicines known as H2 antagonists, e.g. cimetidine and antacids containing calcium carbonate, aluminum hydroxide and magnesium hydroxide).
- Medicines used for asthma and bronchitis (theophylline).
- Medicines used for pain and inflammation (salicylates and

# DILANTIN ORAL SUSPENSION

Phenytoin (125 mg/5 mL)

- corticosteroids).
- Medicines used for sleeplessness, depression and psychiatric disorders (chlordiazepoxide, clozapine, diazepam, disulfiram, fluoxetine, methylphenidate, paroxetine, phenothiazines, trazodone, fluvoxamine, sertraline).
- Medicines used for diabetes (tolbutamide, chlorpropamide).
- Some hormone replacement therapies (estrogens), oral contraceptives (the birth control pill).
- Medicines used for cancer (such as capecitabine, fluorouracil, bleomycin, carboplatin, cisplatin, doxorubicin, methotrexate, irinotecan, paclitaxel and teniposide).
- Medicines used for organ and tissue transplants, to prevent rejection (cyclosporine).
- Muscle relaxants used for surgery (neuromuscular blockers, such as cisatracurium, pancuronium, rocuronium, vecuronium).
- General anaesthetics (such as halothane).
- Methadone, a medicine used to control severe pain and to treat heroin addiction.
- Medicines used to treat parasitic worm infections (such as albendazole and praziquantel).
- St. John's wort (*Hypericum perforatum*), an ingredient used in herbal medicines to treat anxiety and depression.
- Antiretrovirals, used in the treatment of HIV infection (such as fosamprenavir, delavirdine, efavirenz, indinavir, lopinavir/ritonavir, nelfinavir and saquinavir).
- Medicines to treat low blood sugar (such as diazoxide).
- Some products available without a prescription (folic acid, vitamin D).
- Medicines used to lower, cholesterol (such as atorvastatin, fluvastatin, simvastatin).
- Disopyramide used to treat

- irregular heartbeat.
- Furosemide, a diuretic (water tablet), which is used to reduce water retention and high blood pressure.

DILANTIN ORAL SUSPENSION may also interfere with certain laboratory tests that you may be given. If you need to have any medical tests while you are taking DILANTIN, tell your doctor.

## How to use DILANTIN ORAL SUSPENSION

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will tell you to use an accurate measuring device, such as marked measuring spoon or medicine cup to take DILANTIN ORAL SUSPENSION to ensure that you take correct dose.

Your doctor will tell you how much medicine to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines. Your doctor may recommend that you start with a low dose of DILANTIN ORAL SUSPENSION and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions.

General: Dose should be adjusted depending on the individual to provide maximum benefit. Changes in dose (increase or decrease) should not be carried out at intervals shorter than seven to ten days.

Adult Dose: Patients who have received no previous treatment may

be started on one teaspoonful (5 mL) of DILANTIN ORAL SUSPENSION three times daily, and the dose is then adjusted to suit individual requirements. An increase to five teaspoonfuls (25 mL) daily may be made, if necessary.

### Dosing in Special Populations:

- Patients with kidney or liver disease or a condition called hypoalbuminemia in which the level of albumin in the blood is decreased: Your doctor will decide your dose.
- Elderly patients: Less frequent dosing is required.
- Pediatric dose: The starting dose is 5 mg per day for every kg they weigh in two or three equally divided doses, with subsequent dosage individualized to a maximum of 300 mg daily and the recommended daily maintenance dosage is usually 4 to 8 mg per kg of body weight.
- Children older than 6 years and adolescents may require the minimum adult dose (300 mg per day).

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Continue taking DILANTIN ORAL SUSPENSION for as long as your doctor recommends.

### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed

# DILANTIN ORAL SUSPENSION

Phenytoin (125 mg/5 mL)

---

dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of DILANTIN ORAL SUSPENSION may cause unusual eye movements, difficulty in controlling movements and difficulty in speaking. Other signs are shaking, overactive reflex response, lack of strength, slurred speech, blurred vision, low blood pressure, slow heart rate, cardiac arrest, irreversible brain injury, nausea and vomiting. The patient may go into a coma. Death may result from respiratory and circulatory depression.

**While you are using it**

Tell your doctor if you notice any of the following:

- Increase in seizures.
- If you notice bruising, fever, you are looking pale or you have a severe sore throat. These may be the first signs of an abnormality of the blood, including decreases in the number of red cells, white cells or platelets. Your doctor may take regular blood samples to test for these effects.
- Skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) as they may be signs of a hypersensitivity reaction.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), appearing initially as reddish target-like spots or circular patches often with central

blisters on the trunk. Additional signs include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). The rash may progress to widespread blistering or peeling of the skin.

- If you experience confusion or have a severe mental illness, as this may be a sign that you have high amounts of phenytoin in your blood. Your doctor may test your blood to see how much phenytoin is in the blood and may change your dose.

A small number of people being treated with antiepileptics, such as phenytoin, have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Patients, their caregivers and families should be informed that antiepileptic drugs increase the risk of suicidal thoughts and behaviour and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behaviour, or the emergence of suicidal thoughts, behaviour or thoughts about self-harm. Behaviours of concern should be reported immediately to the doctor right away.

- *Things you must do*

Take DILANTIN ORAL SUSPENSION exactly as your doctor has told you and inform your doctor about any condition (such as surgery) in which you are not able to take the medicine orally.

Use an accurately calibrated measuring device when using this medicine to ensure accurate dosing.

Tell all the doctors, dentists and pharmacists treating you that you are taking DILANTIN ORAL SUSPENSION.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not stop taking DILANTIN ORAL SUSPENSION suddenly as it may cause you to suffer seizures more often and you may develop status epilepticus (a state of persistent seizure). To avoid these, your doctor may reduce your dose of DILANTIN ORAL SUSPENSION slowly and start a new antiepileptic medication at a lower dose and gradually increase it.

Do not take any new medicines without consulting your doctor.

Do not give DILANTIN ORAL SUSPENSION to anyone else, even if they have the same symptoms or condition as you.

Do not take any alcoholic beverages without consulting your doctor.

- *Things to be careful of*

*Driving and using machines*

Do not drive or operate potentially dangerous machinery until you know how DILANTIN ORAL SUSPENSION affects you.

**Side Effects**

Like all medicines, DILANTIN ORAL SUSPENSION can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Frequent side effects:

Unusual eye movements, difficulty in controlling movements, slurred speech, abnormal or uncoordinated movements, confusion, feeling of dizziness or spinning, sleeplessness,

# DILANTIN ORAL SUSPENSION

Phenytoin (125 mg/5 mL)

feeling of nervousness for short period of time, twitching muscles, headaches, tingling or numbness in the hands or feet, sleepiness and measles-like reactions.

Other side effects with DILANTIN ORAL SUSPENSION:

- Serious allergic reaction, which causes difficulty in breathing or dizziness.
- Coarsening of the facial features (short noses, flat faces and large head), skin rash and fever with swollen glands, as these may be signs of a hypersensitivity reaction. If these are severe and you also experience pain and inflammation of the joints this could be related to a condition called systemic lupus erythematosus, inflammation of the wall of the arteries, problems with the body's defence against infection.
- Liver problems, such as liver failure, inflammation of liver and liver damage, vomiting, nausea, constipation, swollen lips, bleeding, tender or enlarged gums.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis), appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). The rash may progress to widespread blistering or peeling of the skin, excessive hair growth over the body.
- Abnormality of the blood, including decreases in the number of red cells, white cells or platelets, swelling of the lymph glands.
- Taste disturbances including metallic taste in the mouth.
- Formation of scar tissue, called plaque inside the penis (Peyronie's disease). It can result

in a bent, rather than straight, erect penis.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [nptra.gov.my](http://nptra.gov.my) [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of DILANTIN ORAL SUSPENSION

### - Storage

Keep out of the reach and sight of children.

Store below 30°C.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

Phenytoin Oral Suspension 125 mg/5 mL is provided as an opaque orange suspension with an orange-vanilla-banana odour. The drug product is packaged in a round amber glass bottle or round amber polyethylene terephthalate (PET) bottle, having a polypropylene cap.

### - Ingredients

#### Active ingredient

Phenytoin

#### Inactive ingredients

Magnesium aluminum silicate, Sodium benzoate, Citric acid anhydrous, Carboxymethylcellulose sodium, Glycerin, Sucrose, Polysorbate

40, Alcohol, Vanillin, Banana flavour, Orange oil concentrate, FD & C yellow No. 6 and Purified water.

### - MAL number:

Dilantin Oral Suspension  
125mg/5mL MAL12055031ACRZ

## Manufacturer

Pharmacia and Upjohn Company  
LLC, 7000 Portage Road  
Kalamazoo, Michigan (MI) 49001  
United States (USA)

## Product Registration Holder

Viatis Sdn Bhd  
15-03 & 15-04, Level 15, Imazium,  
No. 8, Jalan SS 21/37,  
Damansara Uptown,  
47400 Petaling Jaya,  
Selangor, Malaysia.

## Date of Revision

18/03/2024

## Serial Number

NPRA (R1/5) 05082024/152

**PLD-DILANTIN-0324**