

DILANTIN® CAPSULES

Phenytoin sodium (30 mg, 100 mg)

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What DILANTIN CAPSULES are used for

DILANTIN CAPSULES are 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 CAPSULES work

DILANTIN CAPSULES belong 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 CAPSULES

- When you must not use it

Do not take DILANTIN CAPSULES

- if you are allergic to Phenytoin or to the inactive ingredients of DILANTIN CAPSULES or other hydantoin medicines;
- if you are taking Delavirdine (used in the treatment of HIV infection).

Pregnancy and lactation

DILANTIN CAPSULES 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 CAPSULES, your doctor can help you decide whether or not to take it during pregnancy. Your doctor will prescribe DILANTIN CAPSULES only if the benefits to you outweigh the risk to your baby and will measure phenytoin

levels in your body periodically.

When appropriate, pregnant women and women of childbearing potential should be counseled about alternative therapeutic options.

Women of childbearing potential who are not planning a pregnancy should be advised regarding the use of effective contraception during treatment.

Tell your doctor if you are breastfeeding or intend to breastfeed. It is not recommended to breastfeed while taking DILANTIN CAPSULES, 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 or kidney problems
- low levels of a protein called albumin in blood
- high levels of bilirubin in blood
- alcohol intake
- blood related disorders
- porphyria (a rare blood pigment disorder)
- diabetes
- a rare drug induced allergic reaction called DRESS or HSS in the past while taking phenytoin or other drugs for epilepsy or you have a family history of this syndrome. The symptoms include fever, rash, blood disorders and problems with other organs.
- weakened immune system
- severe cutaneous adverse reactions (SCARs), serious skin adverse events, such as acute generalized exanthematous pustulosis (AGEP), which is an abrupt skin eruption caused due to some medication, toxic epidermal necrolysis, a severe skin reaction with painful red areas, which blister and peel
- abrupt swelling of the face, area around mouth and upper airway.
- history of osteoporosis
- if you are pregnant as phenytoin may cause fetal harm. Prenatal exposure to phenytoin may increase the risks for congenital malformations and other

adverse development outcomes.

- Taking other medicines

Tell your doctor if you are taking

- Medicines used for heart and circulation problems (dicumarol, digitoxin, digoxin, disopyramide, amiodarone, quinidine, mexiletine, reserpine, warfarin, ticlopidine, and calcium channel blockers, e.g. diltiazem, nifedipine, nimodipine, nisoldipine, verapamil and nifedipine).
- Medicines used to treat blood clots (warfarin, apixaban, dabigatran, edoxaban, rivaroxaban)
- Medicines that stop blood cells from sticking together (Ticagrelor)
- Other medicines used for epilepsy (carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine, phenobarbital, sodium valproate and valproic acid, succinimides, vigabatrin, lacosamide).
- Medicines used to treat fungal infections [amphotericin B and azoles (such as fluconazole, itraconazole, ketoconazole, miconazole, posaconazole and voriconazole)].
- Medicines used for tuberculosis and other bacterial infections (chloramphenicol, erythromycin, isoniazid, rifampin, doxycycline, ciprofloxacin, tetracycline, sulphadiazine, sulphamethizole, sulphamethoxazole – trimethoprim, sulfaphenazole, sulfisoxazole and sulphonamides).
- Medicines used for stomach ulcers (omeprazole, sucralfate, the medicines known as H₂ antagonists, e.g. cimetidine and some antacids).
- Medicines used for asthma and bronchitis (theophylline).
- Medicines used for pain and inflammation (azapropazone, phenylbutazone, salicylates and corticosteroids).
- Medicines used for sleeplessness, depression and psychiatric disorders (chlorthalidone, clozapine, diazepam, disulfiram, fluoxetine, methylphenidate, paroxetine, phenothiazines, trazodone, tricyclic antidepressants, fluvoxamine, sertraline and viloxazine, molindone

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hydrochloride).

- Medicines used for diabetes (tolbutamide, chlorpropamide, glyburide).
- Some hormone replacement therapies (oestrogens), oral contraceptives (the birth control pill).
- Medicines used for cancer (such as capecitabine, fluorouracil, bleomycin, carboplatin, cisplatin, doxorubicin, methotrexate and teniposide).
- Medicines used for organ and tissue transplants, to prevent rejection (cyclosporine).
- Muscle relaxants used for surgery (neuromuscular blockers, such as alcuronium, 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, ritonavir, 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).
- Furosemide, a diuretic (water tablet), which is used to reduce water retention and high blood pressure.

DILANTIN CAPSULES 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 CAPSULES, tell your doctor.

How to use DILANTIN CAPSULES

- 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 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 CAPSULES and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions.

• Dosage in adults for seizures

The recommended starting dose for patients who have not received previous treatment is 300 mg daily, to be taken in three equally divided doses, and the dosage is then adjusted to suit individual requirements. For most adults, the satisfactory maintenance dosage is 300 mg to 400 mg daily to be taken in three to four equally divided doses, respectively. Occasionally, higher doses up to 600 mg daily may be needed.

• Dosage in children for seizures

Children usually start on a dose that depends on their weight (5 mg per day for every kg they weigh) and is given in two or three equally divided dose. The dose is then adjusted up to a maximum of 300 mg per day. A recommended daily maintenance dosage is usually 4 mg/kg to 8 mg/kg. Children over 6 years and adolescents may require the minimum adult dose (300 mg/day).

• Dosage in elderly

Your doctor may lower your dose or reduce the frequency.

• Dosing in patients with kidney and liver disease. Due to an increased fraction of unbound phenytoin in patients with kidney and liver disease, or in those with hypoalbuminemia, the

dosage of phenytoin recommended should be made with caution.

- When to use it

Use as directed by your doctor or pharmacist.

In children, if the daily dosage cannot be divided equally, the larger dose should be given at bedtime.

- How long to use it

Continue taking DILANTIN CAPSULES 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 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 many capsules may cause unusual eye movements, difficulty in controlling movements and difficulty in speaking. Other signs are shaking, overactive reflex response, sleepiness, drowsiness, lack of strength, slurred speech, blurred vision, low blood pressure, nausea, vomiting and irreversible brain injury. The patient may go into a coma. Slow heart rate and cardiac arrest have also been reported. Death may result from respiratory and circulatory depression.

While you are using it

- Things you must do

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Take DILANTIN CAPSULES exactly as your doctor has told you and inform your doctor about any condition in which you are not able to take the capsules such as surgery.

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

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

Call your physician if you develop skin rash.

Maintain a good dental hygiene to avoid bleeding and swelling of gums and other complications.

- Things you must not do

Do not stop taking DILANTIN CAPSULES 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 CAPSULES slowly and start a new antiepileptic medication at a low dose and gradually increase it.

Do not take any new medicines without consulting your doctor.

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

Do not take any alcoholic beverages or other drugs 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 CAPSULES affect you.

Side effects

Like all medicines, DILANTIN CAPSULES 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, 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 CAPSULES

- Serious allergic reaction which causes difficulty in breathing or dizziness.
- Permanent brain injury.
- Repetitive muscle contractions.
- Coarsening of the facial features (short noses, flat faces and large head), bleeding, tender or enlarged gums, excessive hair growth over the body, and Peyronie's disease (development of fibrous scar tissue inside the penis that causes curved, painful erections).
- Liver problems, such as liver failure, inflammation of liver and liver damage, vomiting, nausea, constipation.
- Abnormality of the blood, including decreases in the number of red cells, white cells or platelets.
- Swelling of the lymph glands.
- Cancer of the immune system (Hodgkin's disease).
- Abnormal thyroid function test
- 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.
- Urticaria, which is an outbreak of swollen, pale red bumps or wheals on the skin.
- Change in taste.
- Bone disorders, including osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication or have a

history of osteoporosis.

- Decreased levels of blood calcium, phosphate and vitamin D.
- Pure red cell aplasia (bone marrow stops to produce red blood cells).

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

Storage and Disposal of DILANTIN CAPSULES

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Protect from light and moisture.

- 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

Hard gelatin capsules, bottles of 200's.

30 mg: White opaque body and cap printed with "VTRS" on one side and "VLE 30" on the other in black ink.

100 mg: White opaque body and orange cap printed with "VTRS" on one side and "VLE 100" on the other in black ink.

- Ingredients

- Active ingredient
Phenytoin sodium
- Inactive ingredients
Lactose, sucrose, starch-maize, talc and magnesium stearate.

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The 30 mg capsule shell and band contain titanium dioxide, gelatin and carbon black CI77266 QS; and the 100 mg capsule shell and band contain titanium dioxide, erythrosine CI45430, sunset yellow FCF CI15985, carbon black CI77266 QS, and gelatin.

- *MAL number(s):*

Product Name	Registration Number
Dilantin Capsule 30 mg	MAL19860940ARZ
Dilantin Capsule 100 mg	MAL19860935ARZ

Manufacturer

Viatrix Pharmaceuticals LLC
Km. 1.9 Road 689
Vega Baja, PR 00693 USA.

Product Registration Holder

Viatrix Sdn Bhd
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