

Dilantin(R)

phenytoin, phenytoin sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dilantin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Dilantin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Dilantin is used for

Dilantin 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.

Dilantin 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.

Dilantin is also used to help prevent seizures occurring during or after brain surgery.

Dilantin may also be used to treat a rapid or irregular heart beat.

Dilantin may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may have prescribed Dilantin for another reason. Ask your doctor if you have any questions about why Dilantin has been prescribed for you.

There is no evidence that Dilantin is addictive.

This medicine is available only with a doctor's prescription.

Before you take Dilantin

When you must not take it

Do not take Dilantin if you have an allergy to:

- * phenytoin sodium or phenytoin, the active ingredients in Dilantin, or other hydantoin medicines or any of the ingredients listed at the end of this leaflet
- * methylphenobarbitone or any other barbiturate medicines
- * other medicines used to treat fits and convulsions

Symptoms of an allergic reaction to Dilantin may include:

- * shortness of breath, wheezing or difficulty breathing
- * swelling of the face, lips, tongue or other parts of the body
- * rash, itching or hives on the skin

Do not take Dilantin after the expiry date (EXP) printed on the pack.

Do not take Dilantin if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Dilantin, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- * any other medicines, especially barbiturates or any other anticonvulsant medicines
- * any other substances, such as foods, preservatives or dyes

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

- * liver problems
- * diabetes
- * high blood sugar levels
- * lymphadenopathy, a condition of the lymph glands
- * Systemic Lupus Erythematosus
- * porphyria, a rare blood pigment disorder
- * hypoalbuminaemia, a decrease in serum albumin in the blood, causing water retention
- * anticonvulsant hypersensitivity syndrome, which results in fever, rash and hepatitis
- * a severe skin disorder called Stevens Johnson syndrome
- * toxic epidermal necrolysis, a severe skin reaction with painful red areas, which blister and peel

Tell your doctor if you are pregnant or intend to become pregnant.

Dilantin 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, your doctor can help you decide whether or not to take it during pregnancy.

It is recommended that you do not breastfeed while taking Dilantin, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

If you do breastfeed, watch your baby carefully.

If your baby develops a skin rash, becomes sleepy or has unusual symptoms, don't breastfeed again until you speak to your doctor.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Dilantin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Dilantin may interfere with each other. These include:

- * disulfiram, a medicine used to treat alcoholism
- * other medicines used to treat fits and convulsions, such as vigabatrin, sodium valproate, valproic acid, carbamazepine, ethosuximide, phenobarbital and lamotrigine
- * anticoagulants, medicines used to prevent blood clots
- * some pain relievers, such as salicylates and tramadol
- * benzodiazepines, medicines such as sleeping tablets, sedatives, tranquillisers or medicines to treat anxiety and panic attacks

- * medicines used to treat mood or mental disorders such as clozapine, phenothiazines
- * antidepressants such as fluoxetine, paroxetine, sertraline, fluvoxamine
- * corticosteroids such as cortisone and prednisolone
- * cyclosporin, a medicine used to prevent organ transplant rejection and to treat severe rheumatoid arthritis and some severe skin conditions
- * some medicines used to treat cancer
- * medicines used to treat heart problems, such as quinidine, amiodarone, nifedipine, verapamil and diltiazem.
- * some antibiotics and antifungal medicines used to treat infections, such as erythromycin, tetracyclines, ciprofloxacin, sulfonamides, fluconazole, ketoconazole and miconazole
- * isoniazid, a medicine used to prevent and treat tuberculosis (TB)
- * frusemide, a diuretic (fluid tablet), which is used to reduce water retention and high blood pressure
- * some medicines used to treat stomach or duodenal ulcers, such as omeprazole, sucralfate and cimetidine
- * general anaesthetics and muscle relaxants, medicines used during an operation
- * methadone, a medicine used to control severe pain and to treat heroin addiction
- * methylphenidate, a medicine used to treat Attention Deficit Disorder
- * St John's wort (Hypericum perforatum), an ingredient used in herbal medicines to treat anxiety and depression
- * tolbutamide, glibenclamide, chlorpropamide and diazoxide, medicines used to treat diabetes
- * some vitamins such as folic acid and Vitamin D

- * theophylline, a medicine used to treat asthma
- * oral contraceptives (birth control pills)
- * oestrogens, hormones used in oral contraceptives and in hormone replacement therapy

These medicines may be affected by Dilantin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor may advise you to use an additional method of contraception while taking Dilantin.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Dilantin.

How to take Dilantin

How much to take

Your doctor will tell you how much syrup/how many tablets/capsules you will need 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 and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How to take it

Swallow Dilantin capsules whole with at least half a glass of water.

Chew Dilantin tablets before swallowing.

Shake the bottle well and accurately pour the dose with a medicine measure before taking it.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can get a medicine measure from your pharmacist.

When to take it

Take Dilantin at about the same time each day.

Taking Dilantin at the same time each day will have the best effect. It will also help you remember when to take the tablets/capsules/syrup.

Take Dilantin during or immediately after a meal, at about the same time each day.

If you take Dilantin on an empty stomach, it may cause stomach upset.

If you forget to take it

If it is almost time for your next dose (within 4 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

How long to take it

Continue taking Dilantin for as long as your doctor tells you to.

Dilantin helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.

Do not stop taking Dilantin, or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping Dilantin suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone in Australia - 13 11 26; telephone in New Zealand - 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Dilantin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Dilantin

Things you must do

Tell your doctor immediately if you notice any of the following:

- * increase in seizures (fits)
- * yellowing of the skin and/or eyes
- * swelling of the face
- * strong stomach pains
- * generally feeling unwell with tiredness, weakness and vomiting

These symptoms may mean that you have a serious condition affecting your liver. You may need urgent medical attention.

Tell your doctor immediately if you have any thoughts about suicide or self-harm, any unusual changes in mood or behaviour, or you show signs of depression.

Some people being treated with anti-epileptics such as Dilantin have

thoughts of harming or killing themselves.

Patients and caregivers should be alert and monitor for these effects.

Signs and symptoms of suicide include:

- * thoughts or talk of death or suicide.
- * thoughts or talk of self-harm or harm to others
- * any recent attempts of self-harm
- * new or increase in aggressive behaviour, irritability or agitation
- * feelings of depression

Mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs of suicide while taking Dilantin, contact your doctor or a mental health professional right away.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Dilantin.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Dilantin.

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Dilantin.

Tell your doctor if you feel Dilantin is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken Dilantin exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking Dilantin, tell your doctor.

Tell your doctor if you want to take oral contraceptives while taking Dilantin.

You may need a higher dose of oral contraceptives than usual to prevent pregnancy, or you may need to consider other forms of contraception.

If you need to have any medical tests while you are taking Dilantin, tell your doctor.

Dilantin may affect the results of some tests.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not give Dilantin to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Do not take Dilantin to treat any other complaints unless your doctor tells you to.

Do not stop using it unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Dilantin affects you.

As with other anticonvulsant medicines, Dilantin may cause dizziness, light-headedness, weakness, tiredness, decreased coordination in some people. Make sure you know how you react to Dilantin before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Dilantin may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

Be careful when drinking alcohol while taking Dilantin.

Combining Dilantin and alcohol can make you more sleepy, dizzy or

lightheaded. Your doctor may suggest you avoid alcohol while you are being treated with Dilantin.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dilantin.

Dilantin helps most people with epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop taking Dilantin without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * dizziness or light-headedness
- * headache
- * weakness, unsteadiness when walking, reduced co-ordination or slowed reactions
- * mood changes such as nervousness
- * forgetfulness, loss of concentration or confusion
- * difficulty speaking or slurred speech
- * sleeplessness
- * sleepiness
- * nausea (feeling sick) or vomiting
- * constipation
- * bleeding, tender or enlarged gums
- * enlargement of facial features including thickening of lips
- * aching joints

- * uncontrollable jerky eye movements
- * raised red skin rash or itchy skin rash
- * excessive hairiness, especially in women
- * sexual disturbances, such as painful erection
- * tingling or numbness of the hands or feet
- * changes in taste

These are the more common side effects of Dilantin. Mostly these are mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- * unusual changes in mood or behaviour
- * signs of new or increased irritability or agitation.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- * more frequent or more severe seizures (fits)
- * sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body
- * fever, sore throat, swollen glands, mouth ulcers, unusual bleeding or bruising under the skin
- * tiredness, headache, shortness of breath when exercising, dizziness or pale skin
- * persistent nausea or vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and/or eyes, dark coloured urine, light coloured bowel motions, pain in the abdomen
- * sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing (anaphylactic reactions)
- * severe skin rash, itching, hives, blisters or peeling skin, which may be accompanied by fever, chills, headache, swollen glands,

stomach pain or aching joints and muscles

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

If you are of African or Chinese descent or are immune-deficient you may be at a higher risk of developing some of the above mentioned serious side effects. If you belong to this portion of the population, your doctor will discuss the risks versus the benefits with you.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people. Some of these side effects (for example, changes in thyroid function, structure of bones, high cholesterol or blood pressure) can only be found when your doctor does blood tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Dilantin

Storage

Keep your tablets and capsules in the bottle until it is time to take them.

If you take the tablets or capsules out of the bottle they will not keep well.

Keep your tablets/capsules/syrup in a cool dry place where the temperature stays below 25 degrees C.

Do not store Dilantin or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Dilantin or the capsules/tablets/syrup have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Dilantin capsules 100 mg - white and orange capsules that are marked Parke Davis on one side and P-D 100 on the other side. They are available in bottles of 200 capsules.

Dilantin Capsules 30 mg - white capsules marked Parke Davis on one side and P-D 30 on the other side. They are available in bottles of 200 capsules.

Dilantin Infatabs 50 mg - yellow, chewable, triangular tablets. They are marked P-D 007 on one side and a break bar on the other side. They are available in bottles of 200 tablets.

Dilantin Paediatric Suspension - a reddish-pink suspension which is available in a 500 mL bottle.

Ingredients

* Each white and orange Dilantin Capsule contains 100 mg of the active ingredient phenytoin sodium.

Inactive ingredients are sucrose, lactose, starch-maize, purified talc, magnesium stearate, titanium dioxide, sunset yellow FCF CI15985, erythrosine CI45430, carbon black CI77266 and gelatin

* Each white Dilantin Capsule contains 30 mg of the active ingredient phenytoin sodium. Inactive ingredients are sucrose, magnesium stearate, starch-maize, purified talc, titanium dioxide, carbon black CI77266 and gelatin.

* Each Dilantin Infatab contains the active ingredient phenytoin 50 mg. Inactive ingredients are sucrose, sunset yellow FCF CI15985, starch- maize, quinoline yellow CI47005, saccharin sodium, magnesium stearate, purified talc and spearmint flavour.

* Dilantin Paediatric Suspension contains the active ingredient phenytoin 30 mg/5 mL. Inactive ingredients are sodium benzoate, sucrose, glycerol, aluminium magnesium silicate, carmellose sodium, polysorbate 40, vanillin, orange oil terpeneless, ethanol, carmoisine CI4720, sunset yellow FCF CI5985, citric acid monohydrate, hydrochloric acid, banana flavour and purified water.

Supplier

Dilantin is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114 Australia
Toll Free Number: 1800 675 229

Dilantin is supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand
Toll Free Number: 0800 736 363

**Australian Registration
Numbers:**

Dilantin 100 mg AUST R 14305

Dilantin 30 mg AUST R 14306

Dilantin Infatabs AUST R 14308

Dilantin Paediatric AUST R 14309

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