DILANTIN®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using DILANTIN, speak to your doctor or pharmacist.

1. Why am I taking DILANTIN?

DILANTIN contains the active ingredient phenytoin sodium. DILANTIN is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits).
For more information, see Section 1. Why am I taking DILANTIN? in the full CMI.

2. What should I know before I take DILANTIN?

Do not take if you have ever had an allergic reaction to phenytoin sodium or other hydantoin medicines, methylphenobarbitone or any other barbiturate medicines, other medicines used to treat seizures and convulsions or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or breastfeeding or plan to become pregnant or breastfeed.**
For more information, see Section 2. What should I know before I take DILANTIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DILANTIN and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take DILANTIN?

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. More instructions can be found in Section 4. How do I take DILANTIN? in the full CMI.

5. What should I know while taking DILANTIN?

Things you should do	• Tell your doctor, dentist or pharmacist you visit that you are using DILANTIN. • Tell your doctor immediately if you have any thoughts about suicide or self-harm or have any symptoms of a serious condition affecting your liver. • Tell your doctor if you become pregnant while taking DILANTIN.
Things you should not do	• Do not stop taking DILANTIN or use to treat any other complaints unless your doctor tells you to. • Do not give DILANTIN to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how DILANTIN affects you. • Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.
Drinking alcohol	• Be careful when drinking alcohol while taking DILANTIN as this can make you more sleepy, dizzy or lightheaded.
Looking after your medicine	• Keep your medicine in a cool dry place where the temperature stays below 30°C. • Keep your capsules in the bottle until it is time to take them.

For more information, see Section 5. What should I know while taking DILANTIN? in the full CMI.

6. Are there any side effects?

Less serious side effects: nausea, vomiting, constipation, dizziness, headache, weakness, reduced coordination, confusion, difficulty speaking, sleeplessness or sleepiness, enlarged gums, enlargement of facial features, raised red skin rash. **Serious side effects**: unusual changes in mood or behaviour, signs of new or increased irritability or agitation.
More serious side effects: thoughts about suicide, fever, unusual bruising under the skin, persistent nausea or vomiting, yellowing of the skin and/or eyes, strong stomach pains, more frequent/severe seizures, sudden uncontrollable muscle spasms, sudden signs of allergy, severe skin rash.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

DILANTIN®

Active ingredient(s): Phenytoin sodium

Consumer Medicine Information (CMI)

This leaflet provides important information about using DILANTIN. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking DILANTIN.**

Where to find information in this leaflet:

1. Why am I taking DILANTIN?
2. What should I know before I take DILANTIN?
3. What if I am taking other medicines?
4. How do I take DILANTIN?
5. What should I know while taking DILANTIN?
6. Are there any side effects?
7. Product details

1. Why am I taking DILANTIN?

DILANTIN contains the active ingredient phenytoin sodium. 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 (fits) do not happen.

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

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

2. What should I know before I take DILANTIN?

Warnings

Do not take DILANTIN if:

- you have an allergy to:
  - phenytoin sodium, the active ingredient in DILANTIN or other hydantoin medicines
  - methylphenobarbitone or any other barbiturate medicines
  - other medicines used to treat seizures and convulsions
  - any of the ingredients listed at the end of this leaflet.
    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.
- you are taking delavirdine, a medicine used in the treatment of HIV infection.
- packaging is torn or shows signs of tampering.

Always check the ingredients to make sure you can take DILANTIN.

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

Check with your doctor if you:

- have allergies to any other medicines, especially barbiturates or any other anticonvulsant medicines, any other substances such as foods, preservatives or dyes.
- have any other medical conditions
  - liver problems
  - heart 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
  - hypersensitivity syndrome, which results in fever, rash, blood disorders 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.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant. It is very important to control your seizures while you are pregnant. Your doctor can help you decide if it is necessary for you to take DILANTIN during pregnancy. DILANTIN has been known to cause abnormalities and malignancies in newborns, delaying their growth and causing other harmful side effects.

Talk to your doctor if you are breastfeeding or plan to breastfeed. It is not recommended to breastfeed while taking DILANTIN, as it may pass through breast milk and affect your baby. **If you do breastfeed, watch your baby carefully.** If your baby develops a skin rash, becomes

difficult to wake 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with DILANTIN and affect how it works. These include:

- disulfiram, a medicine used to treat alcoholism
- other medicines used to treat seizures and convulsions
- warfarin, a medicine used to prevent blood clots
- some pain relievers, such as salicylates and tramadol
- benzodiazepines, medicines used as sleeping tablets, sedatives, tranquillisers, or to treat anxiety and panic attacks
- medicines used to treat mental illness such as clozapine, phenothiazines
- medicines used to treat depression
- medicines used to lower cholesterol
- corticosteroids such as cortisone and prednisolone
- ciclosporin, 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
- some medicines used to treat heart problems
- some antibiotics and antifungal medicines used to treat infections
- isoniazid, a medicine used to prevent and treat tuberculosis (TB)
- antiretrovirals, used in the treatment of HIV infection
- medicines used to treat parasitic worm infections
- furosemide, 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
- some medicines used to control diabetes, such as tolbutamide, glibenclamide, chlorpropamide and diazoxide
- some vitamins such as folic acid and vitamin D
- theophylline, a medicine used to treat asthma
- estrogens, a hormone used in oral contraceptives (birth control pills) and in hormone replacement therapy. **Your doctor may advise you to use an additional method of contraception while taking DILANTIN.**

These medicines may be affected by DILANTIN or may affect how well it works. Your doctor will tell you if you need different amounts of your medicine, or if you need to take different medicines.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DILANTIN.

4. How do I take DILANTIN?

How much to take

- 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 and slowly increase the dose to the lowest amount needed to control your epilepsy, convulsions or seizures.
- **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 label, ask your doctor or pharmacist for help.

When to take DILANTIN

- **DILANTIN should be taken 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 your medicine.
- **Take DILANTIN during or immediately after a meal.** This will help prevent stomach upset.

How to take DILANTIN

- **Capsules**: swallow whole with at least half a glass of water.
- **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 forget to take DILANTIN

DILANTIN should be taken regularly at the same time each day.

If you miss your dose at the usual time and 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 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.

If you take too much DILANTIN

If you think that you or anyone else may have taken too much DILANTIN, urgent medical attention may be needed.

You must immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking DILANTIN?

Things you must do

- 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.
- 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 including tests for thyroid function.
- 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.

Call your doctor straight away 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.
- **If you become pregnant while taking DILANTIN**
- **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 increased 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.

Remind any doctor, dentist or pharmacist you visit that you are taking DILANTIN.

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 taking it unless your doctor tells you to.

Things to be careful of

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DILANTIN affects you.

As with other anticonvulsant medicines, DILANTIN may cause dizziness, light-headedness, weakness, tiredness, and decreased coordination in some people.

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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Looking after your medicine

- Keep your capsules in the bottle until it is time to take them. If you take the capsules out of the bottle they will not keep well.
- Keep your medicine in a cool dry place where the temperature stays below 30°C Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
  - in the bathroom or near a sink, or
  - in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

If your doctor or pharmacist tells you to stop taking DILANTIN and you no longer need it or after the expiry date printed on the pack

Getting rid of any unwanted medicine.

Take it to any pharmacy for safe disposal.

6. Are there any side effects?

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

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. Sometimes they are serious, most of the time they are not. However, some side effects may need medical attention.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• bleeding, tender or enlarged gums • enlargement of facial features including thickening of lips • dizziness or light-headedness • headache • weakness, unsteadiness when walking, reduced coordination or slowed reactions • forgetfulness, loss of concentration or confusion • difficulty speaking or slurred speech • sleeplessness or sleepiness • nausea (feeling sick) or vomiting • constipation • aching joints • 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	**Speak to your doctor if you have any of these less serious side effects** These are the more common side effects of DILANTIN. Mostly these are mild and short-lived.

Serious side effects

Serious side effects	What to do
• unusual changes in mood or behaviour • signs of new or increased irritability or agitation	**Call your doctor as soon as possible if you notice any of these serious side effects.** The above list includes serious side effects that may require medical attention.

Very serious side effects	What to do
• thoughts about suicide or self-harm • fever, sore throat, swollen glands, mouth ulcers, unusual bleeding or bruising under the 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 • more frequent or more severe seizures (fits) • sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body • tiredness, headache, shortness of breath when exercising, dizziness or pale skin • sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue, throat or	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Very serious side effects	What to do
other parts of the body, shortness of breath, wheezing or difficulty in swallowing or 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 • slow heartbeat. You may experience severe fatigue, weakness, sweating or fainting	

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 or pharmacist if you notice anything else that may be 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

DILANTIN is only available with a doctor's prescription.

What DILANTIN contains

DILANTIN 100 mg capsule

Active ingredient (main ingredient)	Phenytoin sodium
Other ingredients (inactive ingredients)	• lactose monohydrate • Confectioner's sugar (ID 1749) • purified talc • magnesium stearate • titanium dioxide • sunset yellow FCF • erythrosine • carbon black • gelatin
Potential allergens	Lactose and sugars

DILANTIN 30 mg capsule

Active ingredient (main ingredient)	Phenytoin sodium
Other ingredients (inactive ingredients)	• lactose monohydrate • Confectioner's sugar (ID 1749) • magnesium stearate • purified talc • titanium dioxide • carbon black • gelatin
Potential allergens	Lactose and sugars

Do not take DILANTIN if you are allergic to any of these ingredients.

What DILANTIN looks like

DILANTIN capsules 30 mg - size 4 hard gelatin capsule with a white, opaque body and cap printed with "VTRS" on one side and "VLE 30" on the other in black ink. Available in a bottle of 200 capsules. (AUST R 295264)

DILANTIN capsules 100 mg - size 3 hard gelatin capsule with white, opaque body and orange cap, printed with a "VTRS" on one side and "VLE 100" on the other in black ink. Available in a bottle of 200 capsules. (AUST R 295265)

Who distributes DILANTIN

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Phone: 1800 274 276

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