

DBL™ Phenytoin Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with DBL Phenytoin Injection?

DBL Phenytoin Injection contains the active ingredient phenytoin. DBL Phenytoin Injection is used to control epilepsy. It can also be used to prevent seizures during or after brain surgery and to treat a rapid or irregular heartbeat.

For more information, see Section [1. Why am I being treated with DBL Phenytoin Injection?](#) in the full CMI.

2. What should I know before treatment with DBL Phenytoin Injection?

Do not start treatment if you have ever had an allergic reaction to phenytoin, or to a group of medicines called hydantoins 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, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before treatment with DBL Phenytoin Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Phenytoin Injection 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 is DBL Phenytoin Injection given?

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight. DBL Phenytoin Injection is given as a slow injection into a vein. It must only be given by a doctor or nurse.

More instructions can be found in Section [4. How is DBL Phenytoin Injection given?](#) in the full CMI.

5. What should I know during treatment with DBL Phenytoin Injection?

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| Things you should do | <ul style="list-style-type: none">• Call your doctor straight away if you notice any of |
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| | <p>the following: increase in seizures (fits), yellowing of the skin and/or eyes, swelling of the face, strong stomach pains and generally feeling unwell with tiredness, weakness and vomiting, any thoughts of suicide or self harm, or other mood changes.</p> <ul style="list-style-type: none"> ● You should use effective contraception advised by your doctor during treatment and for one month after stopping treatment. ● Call your doctor straight away if you become pregnant or think you may be pregnant. ● Remind any doctor, nurse, pharmacist or dentist you visit that you are using this medicine |
| <p>Things you should not do</p> | <ul style="list-style-type: none"> ● Do not stop treatment of this medicine suddenly without checking with your doctor. |
| <p>Driving or using machines</p> | <ul style="list-style-type: none"> ● Be careful before you drive or use |

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| | any machines or tools until you know how DBL Phenytoin Injection affects you. This medicine may cause dizziness, lightheadedness and tiredness. |
| Drinking alcohol | <ul style="list-style-type: none"> • Your doctor may suggest you avoid alcohol while you are being treated with this medicine. • Drinking alcohol while using this medicine can make you more sleepy, dizzy or light-headed. |

For more information, see Section [5. What should I know during treatment with DBL Phenytoin Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects include: pain or redness at the injection site, nervous system related issues (e.g. drowsiness, confusion, nervousness), gastrointestinal related issues (e.g. nausea or vomiting), changes to the skin, hair and mouth, eye-related issues, sexual disturbances, breast enlargement in males. Serious side effects include: swelling, discolouration and pain below the injection site; changes in behaviour thinking or mood

(e.g. thoughts of suicide or self-harm); sudden onset of uncontrollable muscle spasms; numbness or weakness of the arms or legs; persistent nausea or vomiting, loss of appetite, generally feeling unwell, itching, yellowing of the skin and/or eyes, dark coloured urine, light coloured bowel motions, pain in the abdomen, unusual bleeding or bruising under the skin; sudden allergic reaction symptoms; severe skin reactions which may be accompanied by fever, swollen glands, mouth ulcers and other symptoms; respiratory-related issues; heart-related issues and bone fracture.

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.

DBL™ Phenytoin Injection

Active ingredient(s): *phenytoin* (FEN-i-toyn)

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Phenytoin Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Phenytoin Injection.**

Where to find information in this leaflet:

- [1. Why am I being treated with DBL Phenytoin Injection?](#)
- [2. What should I know before treatment with DBL Phenytoin Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Phenytoin Injection given?](#)
- [5. What should I know during treatment with DBL Phenytoin Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with DBL Phenytoin Injection?

DBL Phenytoin Injection contains the active ingredient phenytoin. DBL Phenytoin Injection 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.

DBL Phenytoin Injection is used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many types of seizures, ranging from mild to severe.

DBL Phenytoin Injection is also used to help prevent seizures during or after brain surgery.

It may also be used to treat a rapid or irregular heartbeat.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

There is no evidence that DBL Phenytoin Injection is addictive.

2. What should I know before treatment with DBL Phenytoin Injection?

Warnings

You must not be given DBL Phenytoin Injection if:

1. you are allergic to phenytoin, or to a group of medicines called hydantoinis or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction 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.

Always check the ingredients to make sure you can use this medicine.

2. you have or have had certain types of irregular heartbeat conditions.
3. you are taking delavirdine, a medicine used in the treatment of HIV infection.

If you are not sure whether you should be given DBL Phenytoin Injection, talk to your doctor or pharmacist.

Check with your doctor if you:

- have allergies to:
 - any other medicines, especially any other anticonvulsant medicines
 - any other substances, such as foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
 - depression
 - a lowered resistance to disease
 - thoughts of suicide or self-harm
 - liver problems
 - heart problems
 - low blood pressure
 - diabetes

- kidney problems
 - a rare blood pigment disorder called porphyria
 - lymphadenopathy, a condition of the lymph glands
 - hypoalbuminaemia, a decrease in albumin in the blood, causing water retention
 - a severe skin disorder called Stevens Johnson syndrome
 - toxic epidermal necrolysis, a severe skin reaction with painful red areas which blister and peel
 - anticonvulsant hypersensitivity syndrome, which results in fever, rash and hepatitis.
- take any medicines for any other condition

If you have not told your doctor about any of the above, tell them before you are given this medicine.

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

Check with your doctor if you are pregnant or intend to become pregnant.

DBL Phenytoin Injection may affect your developing baby if you are given it during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to be given this medicine, your doctor can help you decide whether or not you should be given it during pregnancy. Phenytoin has been known to cause abnormalities and malignancies in the newborns,

delaying their growth and causing other harmful side effects.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

DBL Phenytoin Injection passes into breast milk; therefore, there is a possibility that the breastfeed baby may be affected.

If there is a need to consider using this medicine while you are breastfeeding, your doctor will discuss with you the benefits and risks of you being given it.

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 DBL Phenytoin Injection and affect how it works. These include:

- medicines used to treat infections such as amphotericin B, chloramphenicol, doxycycline, erythromycin, fluoroquinolones (such as ciprofloxacin), isoniazid, praziquantel, rifampicin, sulfadiazine, sulfamethoxazole-trimethoprim, tetracycline, fluconazole, voriconazole, posaconazole, albendazole, itraconazole, ketoconazole and miconazole
- medicines used to treat HIV infection including delavirdine, amprenavir, efavirenz, lopinavir/ritonavir, indinavir, nelfinavir, ritonavir, saquinavir, and fosamprenavir

- medicines used to prevent blood clots such as warfarin, apixaban, dabigatran, edoxaban, rivaroxaban and ticagrelor
- disulfiram, a medicine used to treat alcohol dependency
- benzodiazepines, medicines used as sedatives or to treat mental disorders such as anxiety (e.g. chlordiazepoxide and diazepam)
- medicines used to treat mental disorders such as clozapine, haloperidol, phenothiazines and thiothixene
- methylphenidate used to treat ADHD (Attention Deficit Hyperactivity Disorder)
- anticonvulsants, medicines used to treat epilepsy such as barbiturates, carbamazepine, phenobarbital, ethosuximide, lamotrigine, primidone, topiramate, oxcarbazepine, valproate, valproic acid, lacosamide and vigabatrin
- medicines used to treat depression such as tricyclic antidepressants, MAO inhibitors, trazodone and serotonin reuptake inhibitors (such as fluoxetine, sertraline and paroxetine)
- hormones such as oestrogens in hormone replacement therapy and oral contraceptives

Your doctor may advise you to use an additional method of contraception while you are given DBL Phenytoin Injection. You should use effective contraception advised by your doctor during treatment and for one month after stopping treatment.

- muscle relaxants or general anaesthetics (e.g. halothane, cisatracurium and rocuronium), medicines used during an operation

- medicines used to manage heart and blood pressure problems such as, beta blockers, calcium channel blockers, diazoxide, digoxin, disopyramide, dopamine, lignocaine, mexiletine, amiodarone, diltiazem, nifedipine, ticlopidine, nimodipine, quinidine and verapamil
- medicines used to treat cancer such as bleomycin, carboplatin, carmustine, cisplatin, dacarbazine, methotrexate, vinblastine, calcium folinate, doxorubicin, fluorouracil and capecitabine
- some vitamins such as folic acid and vitamin D
- medicines used to treat cholesterol levels such as atorvastatin, simvastatin and fluvastatin
- medicines used to treat stomach ulcers such as cimetidine, omeprazole, ranitidine and sucralfate
- theophylline a medicine used to treat asthma
- medicines used to treat immune conditions such as ciclosporin and corticosteroids
- some pain relievers such as salicylates, azapropazone and phenylbutazone
- L-dopa, a medicine used to treat Parkinson's disease
- frusemide, a medicine used to treat fluid retention
- medicines used to treat diabetes, such as tolbutamide and glibenclamide
- methadone, a medicine used to control severe pain or treat opioid dependence
- St John's Wort (*hypericum perforatum*)
- medicines used in organ transplant such as tacrolimus.

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

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given this medicine.

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

4. How is DBL Phenytoin Injection given?

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

How it is given

DBL Phenytoin Injection is given as a slow injection into a vein. It must only be given by a doctor or nurse.

How many injections will you need

This medicine helps control epilepsy, but will not cure it. Therefore, you may need regular injections. Your doctor will decide how long you should continue to be given DBL Phenytoin Injection.

Treatment with phenytoin should not be stopped suddenly.

If you are given too much DBL Phenytoin Injection

As DBL Phenytoin Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you think that you have been given too much DBL Phenytoin Injection and/or if you experience severe side effects, you should immediately:

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

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose include the side effects listed below in Section [6. Are there any side effects?](#) but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

5. What should I know during treatment with DBL Phenytoin Injection?

Things you should do

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.

- have any thoughts of suicide or self harm, or other mental/mood changes

Antiepileptic drugs, including phenytoin increase the risk of suicidal thoughts or behaviour in patients taking these drugs. You should be careful of worsening depression, suicidal thoughts or behaviour, and/or any unusual changes in mood or behaviour.

You should use effective contraception advised by your doctor during treatment and for one month after stopping treatment.

Call your doctor straight away if you become pregnant or think you may be pregnant.

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

Remind any doctor, nurse, pharmacist or dentist you visit that you are using DBL Phenytoin Injection.

Things you should not do

Do not stop treatment of this medicine suddenly without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Phenytoin Injection affects you.

As with other anticonvulsant medicines, DBL Phenytoin Injection may cause dizziness, lightheadedness and tiredness in some people. Make sure you know how you react to this medicine 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 lightheadedness may be worse.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor may suggest you avoid alcohol while you are being treated with this medicine.

Drinking alcohol while using this medicine can make you more sleepy, dizzy or light-headed.

6. Are there any side effects?

This medicine helps most people with epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. Many of the side effects occur only with long term treatment with phenytoin. 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.

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

Side effects

| Side effects | What to do |
|---|--|
| <p data-bbox="204 432 639 533">Administration site reactions</p> <ul data-bbox="204 568 715 674" style="list-style-type: none"><li data-bbox="204 568 715 674">● pain or redness at the injection site <p data-bbox="204 701 746 801">Nervous system related issues</p> <ul data-bbox="204 837 775 1659" style="list-style-type: none"><li data-bbox="204 837 775 943">● drowsiness or feeling tired<li data-bbox="204 965 552 1010">● sleeplessness<li data-bbox="204 1032 619 1137">● dizziness or light-headedness<li data-bbox="204 1160 459 1205">● headache<li data-bbox="204 1227 775 1384">● weakness, unsteadiness when walking, reduced coordination<li data-bbox="204 1406 603 1451">● muscle twitching<li data-bbox="204 1473 592 1518">● trembling hands<li data-bbox="204 1541 456 1585">● confusion<li data-bbox="204 1608 564 1653">● slurred speech <p data-bbox="204 1686 719 1787">Changes in behaviour, thinking or mood</p> <ul data-bbox="204 1823 756 1980" style="list-style-type: none"><li data-bbox="204 1823 756 1980">● nervousness, excitement, irritability or stuttering | <p data-bbox="813 432 1337 651">Speak to your doctor if you have any of these side effects and they worry you.</p> <p data-bbox="813 685 1286 790">These side effects are usually mild.</p> |

| Side effects | What to do |
|---|-------------------|
| <p>Gastrointestinal-related issues</p> <ul style="list-style-type: none"> ● stomach pain ● nausea or vomiting ● loss of appetite ● loss of weight ● loss of taste ● difficulty in swallowing ● constipation <p>Changes in skin, hair and mouth</p> <ul style="list-style-type: none"> ● bleeding, tender or enlarged gums ● enlargement of facial features including thickening of lips ● raised, red, skin discoloration or rash ● excessive hairiness <p>Eye-related issues</p> <ul style="list-style-type: none"> ● uncontrollable jerky eye movements ● blurred vision <p>Reproductive system issues</p> | |

| Side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> • sexual disturbances, such as painful erection • breast enlargement in males | |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Administration site reactions</p> <ul style="list-style-type: none"> • swelling, discolouration and pain below the injection site <p>Changes in behaviour thinking or mood</p> <ul style="list-style-type: none"> • depression • thoughts of suicide or self-harm • unusual changes in mood or behaviour <p>Nervous system-related issues</p> <ul style="list-style-type: none"> • sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body | <p>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.</p> |

| Serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● numbness or weakness of the arms or legs <p>Liver problems</p> <ul style="list-style-type: none"> ● persistent nausea or vomiting ● loss of appetite, generally feeling unwell ● itching ● yellowing of the skin and/or eyes ● dark coloured urine, light coloured bowel motions, pain in the abdomen <p>Sudden allergic reaction symptoms</p> <ul style="list-style-type: none"> ● rash, itching or hives ● swelling of the face, lips tongue or other parts of the body ● shortness of breath, wheezing or difficulty breathing <p>Severe skin reaction symptoms</p> <ul style="list-style-type: none"> ● severe skin rash, itching, hives, blisters or peeling skin, which may be accompanied by: | |

| Serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ○ fever, chills, headache, swollen glands, stomach pain, sore mouth, inflammation of the eye or penis, hayfever, aching joints and muscles ● swelling and redness of the skin with small pus-filled spots or painful lumps under the skin with a fast heartbeat, fever and weight loss <p>Respiratory-related issues</p> <ul style="list-style-type: none"> ● difficulty breathing, wheezing, chest congestion, cough and phlegm <p>Heart and blood-related issues</p> <ul style="list-style-type: none"> ● changes in heartbeat, sometimes with fainting ● low blood pressure ● shortness of breath, swelling of feet and ankles and face, weight | |

| Serious side effects | What to do |
|---|-------------------|
| <p>increase due to fluid build-up</p> <ul style="list-style-type: none"> ● tiredness, headache, shortness of breath when exercising, chest discomfort, dizziness, lethargy or pale skin ● fever, sore throat, swollen glands, mouth ulcers, unusual bleeding or bruising under the skin <p>Bone-related issues</p> <ul style="list-style-type: none"> ● bone fracture | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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 treatment with any of your medicines.

7. Product details

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

What DBL Phenytoin Injection contains

| | |
|---|---|
| Active ingredient (main ingredient) | Phenytoin sodium |
| Other ingredients (inactive ingredients) | Propylene glycol Ethanol absolute Water for injections Sodium hydroxide Hydrochloric acid |

DBL Phenytoin Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not use this medicine if you are allergic to any of these ingredients.

What DBL Phenytoin Injection looks like

DBL Phenytoin Injection is available in 2 strengths:

- 100 mg/2 mL, 5 x 2 mL ampoules (AUST R 46942)

- 250 mg/5 mL, 5 x 5 mL ampoules (AUST R 46943)

How is DBL Phenytoin Injection stored

DBL Phenytoin Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Who distributes DBL Phenytoin Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedinfo.com.au

This leaflet was prepared in July 2023.

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