

DBL™ Phenytoin Injection BP

Phenytoin (FEN-i-toyn)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Phenytoin Injection.

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 being given DBL Phenytoin Injection against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What DBL Phenytoin Injection is used for

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.

This medicine 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 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.

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

Before you are given DBL Phenytoin Injection

When you must not take it

You must not be given DBL Phenytoin Injection if you have an allergy to phenytoin, the active ingredient in DBL Phenytoin Injection, or to a group of medicines called hydantoins, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to phenytoin 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 should not be given this medicine if you have or have had the following condition:

- certain types of irregular heartbeat.

Do not take this medicine if 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.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

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

Tell 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.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

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

If there is a need to consider taking this medicine while you are breast feeding, your doctor or pharmacist will discuss with you the benefits and risks of you being given it.

Tell your doctor if you have or have had any 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.

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

Taking other medicines

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

Some medicines and DBL Phenytoin Injection may interfere with each other. 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. Antifungals; fluconazole, voriconazole, posaconazole, albendazole, itraconazole, ketoconazole and miconazole

- 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 and ADHD (Attention Deficit Hyperactivity Disorder). Examples of these medicines are chlorthalidone, diazepam, methylphenidate, phenothiazines and trazodone.
- 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 mental disorders such as clozapine, haloperidol, phenothiazines and thiothixene
- medicines used to treat depression such as tricyclic antidepressants, MAO inhibitors 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.
- muscle relaxants or general anaesthetics (eg. Halothane, ciatracurium and rocuronium), medicines used during an operation
- methylphenidate used to treat attention deficit disorder
- medicines used to manage heart and blood pressure problems such as, beta blockers, calcium channel blockers, diazoxide, digoxin, disopyramide, dopamine, lignocaine, mexilitene, 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
- some medicines used to treat ulcers such as cimetidine, omeprazole, ranitidine and sucralfate
- theophylline a medicine used to treat asthma
- medicines used to treat problems of immunity such as cyclosporin 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
- alcohol
- medicines used to treat diabetes, such as tolbutamide and glibenclamide
- methadone, a medicine used to control severe pain or treat heroin addiction
- St John's Wort (*Hypericum perforatum*)
- Medicines used to treat HIV infection including delavirdine, amprenavir, efavirenz, lopinavir/ritonavir, indinavir, nelfinavir, ritonavir, saquinavir, and fosamprenavir
- Medicines used to 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 this medicine.

How DBL Phenytoin Injection is 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 your condition, 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 take too much (overdose)

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 experience severe side effects, tell your doctor immediately, immediately telephone the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand), or go to Accident and Emergency at the nearest hospital.

Symptoms of an overdose include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

Ask your doctor or pharmacist if you have any concerns.

While you are being given DBL Phenytoin Injection

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 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.

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 to be careful of

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

As with other anticonvulsant medicines, DBL Phenytoin Injection may cause dizziness, light-headedness 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 light-headedness may be worse.

Be careful when drinking alcohol while being given DBL Phenytoin Injection. Drinking alcohol while taking this medicine can make you more sleepy, dizzy or light-headed.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Phenytoin Injection.

This medicine 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.

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

You may not experience any of them. Many of the side effects occur only with long term treatment with phenytoin.

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

- dizziness or light-headedness
- headache
- feeling tired
- weakness, unsteadiness when walking, reduced coordination
- mood changes such as nervousness, excitement, irritability or stuttering

- confusion
- slurred speech
- blurred vision
- drowsiness
- sleeplessness
- stomach pain
- nausea or vomiting
- loss of appetite
- loss of weight
- difficulty in swallowing
- constipation
- bleeding, tender or enlarged gums
- enlargement of facial features including thickening of lips
- uncontrollable jerky eye movements
- muscle twitching
- trembling hands
- pain or redness at the injection site
- raised, red, skin discoloration or rash
- excessive hairiness
- sexual disturbances such as painful erection
- breast enlargement in males.

These side effects are usually mild.

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

- depression
- thoughts of suicide or self-harm
- unusual changes in mood or behaviour
- 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, chest discomfort, dizziness, lethargy or pale skin
- 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
- 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
- severe skin rash itching, hives, blisters or peeling skin, which may be accompanied by fever, chills, headache, swollen glands, stomach pain, sore mouth, inflammation of the eye or penis, hayfever or 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
- fever, difficulty breathing, wheezing, chest congestion, cough and phlegm
- changes in heartbeat, sometimes with fainting
- shortness of breath, swelling of feet and ankles and face, weight increase due to fluid build-up
- numbness or weakness of the arms or legs
- bone fracture
- low blood pressure.

These may be serious side effects. You may need urgent medical attention.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using DBL Phenytoin Injection

Storage

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 25C.

Product description

What it looks like

Include colour, markings, any tablet scoring, colour and consistency of liquids, pack sizes, etc.

Ingredients

Active ingredients:

Each ampoule contains

- 100mg of Phenytoin sodium per 2mL,
- 250mg of Phenytoin sodium per 5mL

Other ingredients:

- Propylene glycol
- Ethanol alcohol
- Water for injections
- Sodium hydroxide
- Hydrochloric acid.

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

Supplier

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

ARTG numbers:

- 100mg/2mL, 5 x 2 mL ampoules AUST R 46942
- 250mg/5mL, 5 x 5 mL ampoules AUST R 46943

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