

PHENYTOIN SANDOZ® INJECTION

Phenytoin sodium Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Phenytoin Sandoz.

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 using this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Phenytoin Sandoz is used for

Phenytoin Sandoz 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.

Phenytoin Sandoz contains the active ingredient, phenytoin. Phenytoin belongs to a group of medicines known as anticonvulsants. These drugs are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Phenytoin Sandoz is also used to help prevent seizures during or after brain surgery. It may also be used to treat a rapid or irregular heartbeat.

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

Your doctor may have prescribed it for another reason.

There is no evidence that Phenytoin Sandoz is addictive.

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

Before you are given Phenytoin Sandoz

When you must not be given it

You must not be given this medicine if you have an allergy to:

- Phenytoin sodium or phenytoin, the active ingredients, or any other ingredients listed at the end of this leaflet under Product Description
- a group of medicines called hydantoin or other similar medicines such as methylphenobarbitone or any other barbiturate medicines, succinimides, oxazolidinediones and other related compounds
- other medicines used to treat fits and convulsions.

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.

You must not be given this medicine if you have had any of the following medical conditions:

- certain types of irregular heartbeat.

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should be given this medicine, talk to your doctor, nurse or pharmacist.

Before you are given it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant, or plan to become pregnant.

Your doctor can discuss with the risks and benefits involved.

Phenytoin Sandoz 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 Phenytoin Sandoz, 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.

Phenytoin Sandoz 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

breastfeeding, 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 of the following medical conditions:

- depression
- thoughts of suicide or self-harm
- kidney disease
- liver disease
- low blood pressure
- diabetes
- heart problems
- porphyria, a rare blood pigment disorder
- lymphadenopathy, a condition of the lymph glands
- hypoalbuminaemia, a decrease in albumin in the blood causing water retention
- hypoglycaemia or low sugar in the blood
- high blood sugar levels
- anticonvulsant hypersensitivity syndrome, which results in fever, rash and hepatitis
- toxic epidermal necrolysis, a severe skin reaction with painful red areas, which blister and peel
- systemic lupus erythematosus or Stevens-Johnson syndrome, a rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose & genitals.

If you have not told your doctor about any of the above, tell him/her before you are given Phenytoin Sandoz.

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 Phenytoin Sandoz may interfere with each other. These include:

- medicines used to treat infections such as amphotericin B, chloramphenicol, doxycycline, erythromycin,

ciprofloxacin, fluoroquinolones, isoniazid, praziquantel, rifampicin, sulfonamides, tetracycline, fluconazole, itraconazole, ketoconazole, miconazole and voriconazole

- anticoagulants, medicines used to prevent blood clots such as coumarin anticoagulants, warfarin, clopidogrel and ticlopidine
- disulfiram, a medicine used for long term treatment of alcoholism
- benzodiazepines, or medicines used as sedatives, or to treat mental disorders or anxiety such as diazepam and chlordiazepoxide
- medicines used to treat mental disorders such as clozapine, haloperidol, phenothiazines and thiothixenes,
- anticonvulsants, medicines used to treat epilepsy such as barbiturates, felbamate, succinimides, mephenytoin, carbamazepine, oxcarbazepine, primidone, lamotrigine, topiramate, valproic acid, sodium valproate and vigabatrin
- medicines used to treat depression such as tricyclic antidepressants, MAO inhibitors, fluvoxamine
- paroxetine, fluoxetine and sertraline, medicines used to treat depression, obsessive compulsive disorder, panic and anxiety disorders and/or premenstrual dysphoric disorder
- quetiapine, a medicine used to treat schizophrenia and symptoms of bipolar disorder
- hormones such as oestrogens in hormone replacement therapy and oral contraceptives
- muscle relaxants or general anaesthetics (eg. halothane), 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, frusemide, dopamine, lignocaine, mexilitene, amiodarone, verapamil and quinidine

- medicines used to lower cholesterol such as atorvastatin, fluvastatin and simvastatin
- medicines used to treat cancer such as bleomycin, capecitabine, carboplatin, carmustine, cisplatin, dacarbazine, doxorubicin, fluorouracil, methotrexate, teniposide, vinblastine
- some vitamins such as folic acid, Vitamin D and calcium folinate
- some medicines used to treat stomach ulcers such as antacids, 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, tramadol and phenylbutazone
- levodopa, a medicine used to treat Parkinson's disease
- alcohol
- medicines used to treat diabetes, such as tolbutamide, chlorpropamide and glibenclamide
- methadone, a medicine used to control severe pain or treat heroin addiction
- HIV antiviral medicines to treat human immunodeficiency virus (HIV) infection such as delavirdine, amprenavir, efavirenz, lopinavir/ritonavir, indinavir, nelfinavir, ritonavir, saquinavir
- St. John's Wort (*Hypericum perforatum*), a herbal remedy..

These medicines may be affected by Phenytoin Sandoz, or may affect how well it works. You may need different amounts of your

medicines, or you may need to be given different medicines.

Your doctor may advise you to use an additional method of contraception while being given Phenytoin Sandoz.

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

How Phenytoin Sandoz is given

Phenytoin Sandoz must only be given by a doctor or a nurse.

Phenytoin Sandoz is given as a slow injection into the vein.

Your doctor will decide what dose and how long you will receive Phenytoin Sandoz. This depends on factors such as your weight, your condition and whether you are using any other medicines.

Phenytoin Sandoz 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 Phenytoin Sandoz.

Treatment with phenytoin should not be stopped suddenly.

If you have been given too much (overdose)

As Phenytoin Sandoz will be 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 after being given phenytoin, tell your doctor immediately.

Alternatively, telephone the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much Phenytoin

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

You may need urgent medical attention.

Symptoms of a phenytoin overdose may include:

- slurred speech
- blurred vision
- tremor
- lack of coordination
- unusually increased reflexes
- feeling of tiredness or lack of energy
- jerky eye movements
- confusion
- dizziness or drowsiness
- slow heartbeat
- nausea and vomiting.

While you are being given Phenytoin Sandoz

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.

In some patients (usually younger patients), tenderness, swelling, or bleeding of the gums (gingival hyperplasia) may appear soon after treatment with Phenytoin Sandoz is started. To help prevent this, brush and floss your teeth carefully and regularly and massage your gums. If you have any questions about how to take care of your teeth and gums, or if you notice any tenderness, swelling, or bleeding of

your gums, check with your doctor or dentist.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given Phenytoin Sandoz.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Phenytoin Sandoz.

If you plan to have surgery or have emergency treatment, tell your doctor or dentist that you are being given Phenytoin Sandoz.

Tell your doctor if you feel Phenytoin Sandoz is not helping your condition.

Your doctor may need to change your medicine.

If you become pregnant while being given Phenytoin Sandoz, tell your doctor.

Tell your doctor if you want to take oral contraceptives while being given Phenytoin Sandoz.

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

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

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.

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 given this medicine contact your doctor or a mental health professional right away.

Tell your doctor if you need to have any medical tests while being given Phenytoin Sandoz.

Phenytoin Sandoz 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 to be careful of

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

As with other anticonvulsant medicines, Phenytoin Sandoz may cause dizziness, drowsiness, light-headedness and tiredness in some people. Make sure you know how you react to Phenytoin Sandoz before you drive a car, operate machinery or do anything that may be dangerous if you are affected.

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

Phenytoin Sandoz may cause drowsiness, dizziness or sleepiness in some people and affects alertness.

Be careful when drinking alcohol while being given Phenytoin Sandoz.

Combining Phenytoin Sandoz and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest that you avoid alcohol while you are being treated with Phenytoin Sandoz.

If you have to test your urine for sugar while being given Phenytoin Sandoz, make sure your doctor knows which type of test you use.

Phenytoin Sandoz may affect the results of some of these tests.

Side effects

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

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- rapid, uncontrollable movements of the eye
- slurred speech
- clumsiness and lack of coordination
- forgetfulness, loss of concentration or confusion
- sleeplessness or sleepiness
- trembling hands/tremors
- mood changes such as nervousness, excitement, irritability or stuttering
- headaches
- feeling tired
- dizziness or light-headedness
- nausea or vomiting
- stomach pain
- difficulty in swallowing
- loss of taste or appetite
- weight loss
- constipation
- muscle twitching
- skin rash
- joint pain

- fever
- bleeding, tender or gum inflammation
- enlargement of facial features, including thickening of the lips, widening of the nasal tip and protrusion of the jaw
- breast enlargement in males
- excessive hair growth
- pain or redness at the injection site
- sexual disturbances such as painful erection
- unusual tiredness or weakness
- quick shallow breathing
- changes in taste
- chest discomfort.

These side-effects are usually mild.

If any of the following happen, tell your doctor, pharmacist or nurse or go to Accident and Emergency at your nearest hospital:

- 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 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, hay fever or aching joints and muscles
- 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, weight increase due to fluid build-up
 - numbness or weakness of the arms or legs.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

- unusual changes in mood or behaviour
- thoughts of suicide or self harm
- signs of new or increased irritability or agitation

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

Other side effects not listed above may also occur in some patients. 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.

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.

After using Phenytoin Sandoz

Storage

Phenytoin Sandoz will be stored in the pharmacy or on the hospital ward. The ampoule is kept in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

Phenytoin Sandoz is a clear, colourless solution.

Ingredients

Active ingredient:
Each ampoule contains 50mg/mL phenytoin (as sodium).

Inactive ingredient:

- propylene glycol
- ethanol
- sodium hydroxide
- water for injections.

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

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 634 500

Novartis New Zealand Ltd
PO Box 99102
Newmarket, Auckland 1149
New Zealand
Tel: 0800 354 335

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Australian Registration Numbers:

250mg/5mL: AUST R 117865

100 mg/2mL: AUST R 117872