



Phenytoin Sodium Injection USP 100mg/2ml, 250mg/5ml

Package leaflet: Information for the user

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Phenytoin Injection is and what it is used for
2. What you need to know before you use Phenytoin Injection
3. How to use Phenytoin Injection
4. Possible side effects
5. How to store Phenytoin Injection
6. Contents of the pack and other information

1. What Phenytoin Injection is and what it is used for

Phenytoin Injection contains the active substance phenytoin which is one of a group of medicines called hydantoin.

Phenytoin Injection is a medicine which is used to control status epilepticus (serious condition in which seizures (fits) continue for hours or days) or to prevent fits during or after neurosurgery. It can also be used to correct some heart rhythm abnormalities.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before

you use Phenytoin Injection Do not use

Phenytoin Injection:

- if you are allergic to phenytoin, medicines of the same class (hydantoin) or any of the ingredients of this medicine (listed in section 6)
- in patients with certain heart conditions

If possible, tell your doctor if any of the above applies to you before this medicine is used.

This medicine must not be injected into an artery. See section 3 for the correct method of administration.

Warning and precautions

Take special care with Phenytoin Injection

A small number of people being treated with anti-epileptics such as phenytoin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

There is a risk of harm to the unborn child if Phenytoin Injection is used during pregnancy. Women of childbearing age should

use effective contraception with Phenytoin Injection (see Pregnancy, contraception in women, and breast-feeding).

Serious skin side effects can rarely occur during treatment with Phenytoin Injection. This risk may be associated with a variant in genes in a subject of Chinese or Thai origin. If you are of such origin and have been tested positively carrying this genetic variant (HLA-B*1502), discuss this with your doctor before taking Phenytoin Injection. Some evidence suggests that black patients are also at increased risk of these reactions. In the Caucasian and Japanese population frequency of the genetic variant (HLA-B*1502) is extremely low therefore risk of developing serious skin side effects cannot be concluded.

A combination of phenytoin, radiation therapy to the head and gradual reduction in treatment with corticosteroids may also be associated with the development of serious skin side effects.

Irritation and swelling can occur at and around the site of injection with phenytoin. Build up of fluid beneath the skin, change in colour of the skin and pain may also occur following peripheral intravenous phenytoin injection.

In rare cases, patients taking phenytoin have experienced problems with their internal organs. Outward signs include fever, rash and swollen lymph nodes (isolated small raised lumps under the skin) within 2-12 weeks of beginning treatment. The risk may be increased in black patients, patients who have a family history of or who have experienced these problems in the past and those with decreased ability to fight infections (also known as immunosuppression).

Special care needs to be taken with Phenytoin Injection

- if you have a liver or kidney disorder

- if you suffer from diabetes
- if you suffer from low blood pressure
- if you suffer from heart problems
- if you have a condition called porphyria

If possible, tell your doctor if any of the above applies to you before this medicine is used.

Other medicines and Phenytoin

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Special care is needed if you are taking/using other medicines as some could interact with phenytoin, for example:

- some antibacterials e.g. doxycycline, ciprofloxacin, chloramphenicol, isoniazid, rifampicin, and other sulphonamides
- some antifungals i.e. amphotericin B, ketoconazole, fluconazole, miconazole and itraconazole
- some coumarin anticoagulants, e.g. warfarin and dicoumarol
- medicines used to control diabetes e.g. insulin or oral anti-diabetic agents (eg tolbutamide)
- some pain killers and anti-inflammatory medicines, i.e. phenylbutazone and salicylates such as aspirin
- some medicines used to control anxiety, e.g. chlordiazepoxide, diazepam
- barbiturates, e.g. phenobarbitone and amylobarbitone
- corticosteroids (used in numerous situations to aid the body's healing process)
- some medicines used to treat mental problems such as

psychoses and depression, e.g. haloperidol, methylphenidate, monoamine oxidase inhibitors, trazodone, thioxanthenes, fluoxetine, fluvozamine, sertraline and tricyclic antidepressants

- oral contraceptives and other medicines which mimic female hormones, e.g. oestrogen and ethinyloestradiol
- antiepileptic medicines, e.g. carbamazepine, ethosuximide, mephenytoin, primidone, sodium valproate, sulthiame, valproic acid, oxcarbazepine and trimethadione
- halothane (an inhaled general anaesthetic)
- some anti-ulcer medicines, e.g. cimetidine and ranitidine
- medicines taken to help the heart, i.e. aspirin, beta-blockers, diazoxide, digoxin, diltiazem, disopyramide, dopamine, frusemide, mexiletine, nifedipine, quinidine, reserpine, amiodarone and verapamil
- medicines often taken while undergoing cancer treatment, i.e. bleomycin, calcium folinate, carboplatin, carmustine, cisplatin, dacarbazine, fluorouracil and vinblastine
- St John's wort - The herbal remedy St John's wort (*Hypericum perforatum*) should not be taken at the same time as this medicine. If you already take St John's wort, consult your doctor before stopping the St John's wort preparations
- nelfinavir, used in the treatment of HIV
- others which you may recognise by name: ciclosporin, disulfiram, folic acid, L-dopa, lignocaine, succinimide, viloxazine, theophylline (a xanthine), methotrexate, omeprazole, ticagrelor and vitamin D

Phenytoin with food and drink and alcohol

The consumption of alcohol, whilst you are being treated

with phenytoin can reduce the effectiveness of treatment or increase the side effects.

Pregnancy, contraception in women and breast-feeding

Pregnancy

If you are pregnant, consult your doctor promptly. You should not stop taking your medicine until you have discussed this with your doctor. Stopping your medication without consulting your doctor could cause seizures which could be dangerous to you and the pregnancy. Your doctor may decide to change your treatment. Closer monitoring of your unborn child should also be considered.

Phenytoin may cause birth defects. If you take phenytoin during pregnancy your baby has a higher risk of having a birth defect. Birth defects which have been reported include facial, skull, nail, finger and heart abnormalities.

If you are of childbearing age and plan to become pregnant, consult your doctor for a preconceptional visit. You should discuss your treatment options with your doctor.

If you take phenytoin during pregnancy, your baby is also at risk for bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this. Moreover, your child should be closely monitored.

Contraception in women

If you are of childbearing age, you should discuss your treatment options and effective methods of birth control with

your doctor. Phenytoin may result in a failure of hormonal contraceptives, hence you should be counselled regarding the use of other effective contraceptive methods.

Breast-feeding

Phenytoin passes into breast milk. You should not take phenytoin if you are breast-feeding.

Children

Phenytoin is used for newborns, infants and children.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use machines if you experience any side effect (e.g. dizziness or drowsiness) which may lessen your ability to do so.

Phenytoin Injection contains ethanol and propylene glycol

This medicinal product contains 10% vol ethanol (alcohol), i.e. up to 1.6 g per 1 g dose of phenytoin, equivalent to 57 ml of a 3.5% vol beer or 14 ml of a 14% vol wine. Harmful to those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

In addition, this medicinal product contains propylene glycol, which can cause alcohol-like symptoms and sodium (1.1 mmol per 5 ml ampoule).

3. How to use Phenytoin Injection

Always use this medicine exactly as your doctor has told you.

Check with your doctor if you are not sure.

This medicine will be given to you by a slow injection via a drip into a vein or, more rarely, via an injection into a muscle.

Recommended Dose

Your doctor will calculate the correct dose of phenytoin for you.

The dose will depend upon your medical condition, your size, your age and how well your kidneys, liver and heart are working. Your doctor will tell how well your liver and kidneys are working from blood and urine samples.

Where treatment is prolonged, blood samples may be taken to check the level of phenytoin in the blood. Subsequent doses may be increased or decreased accordingly.

If you use more Phenytoin Injection than you should

As this medicine will be given to you whilst you are in hospital it is unlikely that you will be given too little or too much, however tell your doctor or pharmacist if you have any concerns.

If you forget to use Phenytoin Injection

Do not take a double dose to make up for a forgotten dose.

If you stop using Phenytoin Injection

Sudden withdrawal of phenytoin treatment in patients susceptible to fits may cause status epilepticus. In such cases, phenytoin dosage reduction should be gradual, perhaps following a switch to a form of phenytoin which can be taken by mouth.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- rash (can be severe resulting in painful reddening and blistering of the skin, eyes, inside of the mouth and ano-genital region and may lead to skin shedding)
- swollen lymph nodes (isolated small raised lumps under the skin)
- chest pains and palpitations

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

If any of the following happen, tell your doctor as soon as possible:

- pain and inflammation at the injection site (in rare instances severe tissue damage has required amputation), some discolouration and pain above the injection site, known as “Purple Glove syndrome” can occur
- tightness of the chest or wheezing
- dizziness/fainting/vertigo
- fever
- persistent pain, tingling or numbness
- contraction of the fingers (bending in to the palm) (Dupuytren’s contracture)
- slurred speech
- muscle twitching and/or rapid uncontrollable eye movements
- fits or seizures
- difficulties associated with muscular movement: loss of

muscle co-ordination, clumsiness or unsteadiness, shaking and loss of muscle tone

- bleeding, tender or enlarged gums (may be reduced by maintaining good oral hygiene and massaging the gums)
- joint pain
- yellowing of the eyes and skin
- confusion
- enlargement of facial features including thickening of the lips
- unusual and excessive hair growth on body and face
- increased sweating
- Peyronie’s disease (a condition where male patients experience a deformation of the penis which may cause pain when the penis is erect)
- unusual tiredness, drowsiness or weakness
- a feeling of nervousness
- loss of appetite and weight
- taste changes
- insomnia
- headache
- nausea/vomiting
- constipation
- DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) that appears initially as flu-like symptoms and a rash on the face and then an extended rash with a high temperature, increased level of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. The consequences can be life-threatening.

There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.



Phenytoin may cause problems with breathing, blood pressure, heart and liver function, blood-sugar levels and blood cell count. Your doctor may do tests to check for these side effects.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Phenytoin Injection

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep in the outer carton to protect from light. Unused portions of opened ampoules must not be stored for later use.

Only clear, colourless solutions should be used. Do not use this medicine if you notice paque, cloudy or discoloured solutions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information What

Phenytoin Injection contains

The active substance is phenytoin sodium. Each millilitre (ml) of solution contains 50 milligrams (mg) of phenytoin sodium.

The other ingredients are ethanol, propylene glycol and Water for Injections. (see section 2

Phenytoin Injection contains ethanol and propylene glycol).

What Phenytoin Injection looks like and contents of the pack

Phenytoin Injection is a clear, colourless solution for injection which comes in glass containers called ampoules.

It is supplied in packs containing 5 x 250 mg/5 ml ampoules.

7.Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m. EST

E-mail: tajgroup@tajpharma.com