



Package leaflet: Information for the user

Phenytoin 50 mg/ml Injection BP phenytoin

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

Talk to your doctor before taking 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 during treatment with Phenytoin Injection (see Pregnancy, breast-feeding and fertility).

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).

Cases of swelling of the face, mouth (lip, gum, tongue) and neck that can lead to life-threatening breathing difficulty have been reported in people being treated with phenytoin. If at any time you have these signs or symptoms immediately contact your doctor.

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 you are of Taiwanese, Japanese, Malaysian or Thai origin and tests have shown that you carry the genetic variant CYP2C9*3

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
- anticoagulants, e.g. apixaban, dabigatran, dicoumarol, edoxaban, rivaroxaban and warfarin
- 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, fluvoxamine, sertraline and tricyclic antidepressants
- oral contraceptives and other medicines which mimic female hormones, e.g. oestrogen and ethinyloestradiol
- antiepileptic medicines, e.g. carbamazepine, ethosuximide, lacosamide, 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, breast-feeding and fertility

Pregnancy

What you should know about the use of antiepileptic drugs in pregnancy

If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.

If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.

You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important your epilepsy is well controlled.

Taking phenytoin during pregnancy increases the chance that the baby may have a physical birth abnormality.

Studies with women treated with phenytoin for epilepsy during pregnancy have shown that around 6 babies in every 100 will have serious physical birth abnormalities. This compares to 2-3 babies in every 100 born to women who don't have epilepsy.

The most common types of serious physical birth abnormalities (major congenital malformations) reported for phenytoin include abnormalities of the lip and palate, heart, skull, nail and finger disorders and growth abnormalities. Some of these may occur together as part of a fetal hydantoin syndrome.

Taking more than one epilepsy medicine at the same time may also increase the risk of physical birth abnormalities. Where possible, your doctor will consider using one epilepsy medicine only to control your epilepsy.

Your doctor may advise you to take folic acid if you're planning to become pregnant and while you're pregnant. Your doctor may adjust your epilepsy medicine when you take folic acid.

Some studies observed that taking phenytoin during pregnancy increases the chance that the baby may have problems affecting learning and thinking abilities.

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,

Intramuscular phenytoin administration may cause pain, necrosis and abscess formation at the injection site.

Incompatibilities

Incompatible with amikacin sulphate, cephalosporin sodium, clindamycin phosphate, and many other drugs. It is recommended that phenytoin sodium is not mixed with other drugs or with any infusion solution other than sodium chloride 0.9%.

Phenytoin Injection BP

The following information is intended for medical or healthcare professionals only. Practical information on the preparation/handling of the medicinal product is provided here.

Intra-arterial administration must be avoided in view of the high pH of the preparation.

Improper administration including subcutaneous or perivascular injection should be avoided.

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, propylene glycol and sodium

Ethanol (alcohol)

This medicine contains 416.4 mg of alcohol (ethanol) in each 5 ml of solution, which is equivalent to 83.3 mg of ethanol per ml. The amount in 5 ml of this medicine is equivalent to 10.4 ml beer or 4.2 ml wine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

Propylene glycol

This medicinal product also contains 2,075 mg propylene glycol in each 5 ml solution of phenytoin, which is equivalent to 415.0 mg of propylene glycol per ml.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Sodium

This medicine contains 24.26 mg sodium (main component of cooking/table salt) in each 5 ml solution, equivalent to 1.2% of the recommended maximum daily dietary intake of sodium for an adult.

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, neck, 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.
- life-threatening skin rashes that cause blistering (this can affect the mouth and tongue)

A decrease in the number of a type of red blood cell (pure red cell aplasia) has also been reported.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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 opaque, 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, propylene glycol and sodium).

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.

Marketing Authorisation Holder

Hospira UK Limited, Walton Oaks, Walton-On-The-Hill, Dorking Road, Tadworth, Surrey, KT20 7NS, UK

Manufacturer

Pfizer Service Company BV
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This leaflet was last revised in 11/2025.

Ref: gxPH 6_0

Instructions for use and handling

For single use. Discard any unused contents.

The product should be visually inspected for particulate matter and discolouration prior to administration.

Phenytoin Injection is suitable for use as long as it remains free of haziness and precipitate.

A precipitate might form if the product has been kept in a refrigerator or freezer. This precipitate will dissolve if allowed to stand at room temperature.

The product will then be suitable for use.

For infusion administration, Phenytoin Injection should be diluted in 50 - 100 ml of normal saline, with the final concentration of phenytoin in the solution not exceeding 10 mg/ml. Administration should commence immediately after the mixture has been prepared and must be completed within one hour (the infusion mixture should not be refrigerated). An in-line filter (0.22 - 0.50 microns) should be used. The diluted form is suitable for use as long as it remains free of haziness and precipitate.