

## Phenobarbitone Injection

*phenobarbital (phenobarbitone) sodium*

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Phenobarbitone Injection. It does not contain all of 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 it against the benefits they expect it will have.

**If you have any concerns about the use of this medicine ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What Phenobarbitone Injection is used for

The active ingredient is called phenobarbital (phenobarbitone) sodium.

It belongs to a group of medicines called barbiturates, which act by inducing sleep and stopping convulsions.

Phenobarbitone Injection is used for treatment of grand mal and psychomotor epilepsy and sedation.

**Ask your doctor if you have any questions about why Phenobarbitone Injection has been prescribed for you.**

Your doctor may have prescribed it for another purpose.

Phenobarbitone Injection is available only with a doctor's prescription.

The use of barbiturates may lead to dependence on this medicine.

#### Before it is given

##### *When it must not be used*

**Phenobarbitone Injection should not be used if you are allergic to:**

- phenobarbital (phenobarbitone) sodium
- any of the other ingredients listed at the end of this leaflet
- any other barbiturate.

Some of the symptoms of an allergic reaction may include red, itchy skin rashes; difficulty breathing; hay fever; swelling of the face or throat or faintness.

**Do not use if you have or have had any of the following medical conditions:**

- porphyria (a rare blood pigment disorder)
- severe anaemia (a disease of the blood with reduced number of red blood cells) if it is due to folate deficiency
- uncontrolled severe asthma
- severe respiratory depression
- uncontrolled diabetes mellitus or sugar diabetes
- acute intoxication with alcohol, hypnotics or analgesics
- intoxication with stimulants or depressant psychotropic agents
- alcoholism or drug dependence
- severe liver or kidney problems
- severe depression or suicidal tendencies
- short or long term serious or chronic pain.

**Phenobarbitone Injection should not be given to unusually overactive children.**

**Do not use after the expiry date (EXP) printed on the pack.**

**Do not use if the packaging is torn or shows signs of tampering.**

*Before you are given it*

**You must tell your doctor if you:**

- are allergic to any other medicines or any foods, dyes or preservatives
- have or have had any other medical conditions or health problems, including:
  - high/low blood pressure
  - heart problems
  - lung problems
  - hyperthyroidism, an overactive thyroid gland
  - hypoadrenalism (borderline), an underfunction of the adrenal gland
  - a depressive illness
  - asthma
- are a heavy drinker
- have a drug dependency.

**Tell your doctor if you are pregnant or intend to become pregnant.**

Phenobarbitone Injection may affect your developing baby if you take it during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take Phenobarbitone Injection, your doctor can help you decide whether or not to take it during pregnancy.

**Tell your doctor if you are breast-feeding or plan to breast-feed.**

This medicine is not recommended for use while breastfeeding as it passes into breast milk and may cause serious side effects to your baby.

Elderly patients are more likely to have less effective kidney or liver function. This may increase the risk of side effects.

**If you have not told your doctor about any of the above, tell them before Phenobarbitone Injection is used.**

##### *Taking other medicines*

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

Some medicines may interact with Phenobarbitone Injection. These include:

- other medications used to treat epilepsy
- anticoagulants, medicines used to treat clots eg. warfarin
- painkillers, paracetamol and stronger narcotic agents
- antidepressants, medicines used to treat depression
- anti-arrhythmics, medicines used to treat irregular heart beats eg. quinidine, disopyramide
- antibiotics and antifungal agents, medicines used to treat infections including AIDS
- calcium channel blockers, medicines used to treat high blood pressure and angina
- antipsychotics, medicines used to treat certain mental and emotional conditions

- chemotherapy drugs, used to treat cancer
- corticosteroids, such as prednisolone, cortisone
- medicines used to treat heart failure eg. digoxin
- oral contraceptives
- immunosuppressive medicines, used to lower your body's resistance to disease e.g. cyclosporin, tacrolimus
- medicines used to stop you from feeling pain, e.g. anaesthetic agents
- disulfiram, a medicine used to treat alcoholism
- urinary alkalinisers
- antihistamines, medicines used to prevent or relieve symptoms of allergy
- theophylline, a medicine used to treat asthma
- beta-blockers e.g. propranolol, used to treat high blood pressure and heart conditions
- other medications that interact with alcohol.

These medicines may be affected by Phenobarbitone Injection or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while being given Phenobarbitone Injection.

#### How it is given

##### *How much is given*

The recommended dose of Phenobarbitone Injection varies depending on your condition. Your doctor will determine how much is appropriate.

##### *How it is given*

Except under unusual circumstances, Phenobarbitone Injection should be administered by a health care professional.

##### *How long to have it for*

Phenobarbitone Injection should be given for as long as recommended by your doctor.

**If symptoms persist, see your doctor.**

##### *If too much is given (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to casualty at your nearest hospital, if you think that you or anyone else may have been given too much Phenobarbitone Injection.**

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

**Also report any other medicine or alcohol (including any barbiturates or narcotics) which has been taken.**

You may need urgent medical attention.

Symptoms of overdose may include weakness, dizziness, lethargy, nausea, vomiting, sweating, underbreathing, shock, impairment of consciousness, collapse of circulation, mental confusion and hypotension.

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## While you are being given it

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### *Things you must do*

**Tell your doctor if you become pregnant while you are being given Phenobarbitone Injection.**

**Tell your doctor if you want to take oral contraceptives while being given Phenobarbitone Injection.**

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

**If you need any medical tests while you are being given Phenobarbitone Injection, tell your doctor as it may affect the results of some tests.**

**Always discuss with your doctor any problems or difficulties during or after being given Phenobarbitone Injection.**

Your doctor may want to take some tests from time to time to help prevent unwanted side effects.

### *Things you must not do*

**Do not use any other medicines while you are being given Phenobarbitone Injection without first telling your doctor.**

**Do not drive or operate machinery while being given this medicine.**

Phenobarbitone Injection may cause drowsiness or dizziness in some people and therefore may affect alertness.

### *Things to be careful of*

Be careful drinking alcohol while using Phenobarbitone Injection. If you drink alcohol, it could make some of the unwanted side effects of this medicine worse. Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while Phenobarbitone Injection is being given.

Some people may experience side effects such as nausea, vomiting, constipation, drowsiness and dizziness, which may further affect the risk when driving or using dangerous machinery.

### *Side effects*

**Tell your doctor or pharmacist as soon as possible if you do not feel well while Phenobarbitone Injection is being given.**

All medicines 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.

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

**Tell your doctor if you notice any of the following common side effects and they worry you:**

- pain or irritation at the site of injection
- rapid heartbeat
- nausea (feeling sick)
- constipation
- dizziness
- lethargy
- vomiting
- skin rashes
- sweating
- dry mouth
- confusion
- faintness
- irritability

- restlessness
- dependency (habit-forming)
- mood changes
- drowsiness
- hyperexcitability
- hangover
- sleep disturbances.

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:**

- signs of infection e.g. fever, chills, sore throat, swollen glands, mouth ulcers
- easy or unusual bleeding or bruising under the skin
- nosebleed
- yellowing of the skin and eyes (jaundice)
- other sudden signs of allergy
- severe skin rash, itching, hives, blisters or peeling skin.

These are very serious side effects.

**Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.**

**Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.**

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

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

You may not experience any of them.

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## After being given it

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### *Storage*

Phenobarbitone Injection is stored in the pharmacy or on the ward. The injection is kept in a cool dry place, where the temperature stays below 25°C.

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## Product description

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### *What it looks like*

Phenobarbitone Injection is a clear, colourless solution in a clear glass 1 mL ampoule.

It is for single use in one patient only.

Available in packs of 5 ampoules.

### *Ingredients*

#### **Active ingredient:**

Each 1 mL ampoule contains phenobarbital (phenobarbitone) sodium 219 mg, equivalent to phenobarbitone 200 mg.

#### **Inactive ingredients:**

- propylene glycol
- ethanol
- water for injections.

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## Sponsor

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