

PACKAGE LEAFLET: INFORMATION FOR THE USER
Phenobarbital Sodium Injection 15mg/ml, 30mg/ml, 60mg/ml or 200mg/ml
Phenobarbital Sodium
(Referred to as Phenobarbital Injection in this leaflet)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Phenobarbital Injection is and what it is used for
2. Before Phenobarbital Injection is given
3. How Phenobarbital Injection will be given
4. Possible side effects
5. How to store Phenobarbital Injection
6. Further information

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

Phenobarbital belongs to a group of drugs known as barbiturates. Barbiturates have antiepileptic properties which mean they help prevent some types of epileptic seizures. They can also make you feel sleepy.

Phenobarbital Injection is used in the treatment of most types of epilepsy except absence seizures (petit mal).

2. Before Phenobarbital Injection is given

Do not use Phenobarbital Injection if:

- You are allergic (hypersensitive) to any barbiturates or any of the ingredients of this medicine (see section 6)
- You suffer from acute intermittent porphyria (a type of blood disorder)
- You suffer from severe breathing difficulties (respiratory depression)
- You suffer from liver or kidney problems

If your problem is not severe your doctor may decide to give you the medicine with caution. Talk to your doctor, they will advise you on your particular situation.

Take special care with Phenobarbital Injection if:

- You have an alcohol or drug problem
- You are pregnant, planning to become pregnant or are breast-feeding
- You are young, elderly or in poor health

If any of the above applies to you, please tell your doctor.

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

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of phenobarbital injection, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

The highest risk of occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson syndrome, toxic epidermal necrolysis with the use of phenobarbital injection, you must not be re-started on phenobarbital injection at any time.

If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Using other medicines:

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Please tell your doctor if you are taking any of the following medicines which may interact with Phenobarbital Injection:

- Any calcium channel blockers (drugs that affect the way calcium passes into certain muscle cells) e.g. diltiazem, felodipine, verapamil, nimodipine, nifedipine
- Coumarin anticoagulants (drugs that reduce the clotting of blood e.g. warfarin)
- Chloramphenicol, doxycycline, metronidazole, telithromycin (antibiotics)
- Cyclosporin (a drug used to suppress the body's immune system)
- Digitoxin, quinidine, disopyramide (drugs used to treat certain heart disorders)
- Griseofulvin (a drug used to treat certain fungal infections)
- Phenylbutazone (an anti-inflammatory drug)
- Rifampicin (used in the treatment of TB)
- Systemic steroids including oral contraceptives (birth control) possibly leading to contraceptive failure
- Theophylline (used to treat asthma)
- Thyroxine (used to treat an under active thyroid)
- Protease inhibitors indinavir, lopinavir, nelfinavira and saquinavir (drugs used to treat HIV)

- Memantine (a drug used to treat Alzheimer's disease)
- Toremifene (an anti-oestrogen used to treat certain types of breast tumour following the menopause)
- Tropisetron (an anti-sickness drug)
- Folic acid or folinic acid
- Vitamin D
- Montelukast (a drug used to treat breathing difficulties)
- Alcohol and strong painkillers (e.g. morphine, codeine)
- Tricyclic antidepressants (e.g. amitriptyline)
- Antiepileptic drugs (e.g. other barbiturates, carbamazepine, lamotrigine, phenytoin and sodium valproate)
- Phenothiazines (mood modifiers e.g. chlorpromazine, fluphenazine and pericyazine)
- Tranquillisers (e.g. diazepam)
- Antipsychotic drugs (e.g. haloperidol)
- St John's wort (*Hypericum perforatum*) for depression
- Voriconazole (a medicine used to treat fungal infections)

If you are in any doubt please tell your doctor of any medication you are taking.

Using Phenobarbital Injection with food and drink:

You are advised NOT to drink alcohol with this medicine.

Pregnancy and breast-feeding:

This medicine should not be given to you if you are pregnant, trying to become pregnant or are breast-feeding, unless your doctor has specifically recommended it.

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

Driving and using machinery:

This medicine may make you feel sleepy. If so, do not drive a car or operate machinery.

Important information about some of the ingredients

Phenobarbital Injection contains propylene glycol which may cause alcohol-like symptoms. If you feel unwell whilst you are being given Phenobarbital Injection you should tell your doctor or nurse.

3. How Phenobarbital Injection will be given

This medicine is an injection and will be given to you by your doctor. Your doctor will determine the dose you require.

Adults

- 50 - 200mg as a single dose
- The injection can be administered under the skin or, into a vein following dilution with water

- Repeated, if necessary after 6 hours
- Up to a maximum of 600mg per day.

Children

- Use with caution
 - 3 - 5mg per kg body weight as a single dose into the muscle
- Your doctor will advise you on your duration of therapy.

If you are given too much Phenobarbital Injection:

If you experience any of the following, tell your doctor immediately:

- Sleepy
- Faint
- Extremely cold
- Your breathing becoming very shallow

If you are at all concerned that you have been given too much of this medicine please tell your doctor.

If you missed a dose of Phenobarbital Injection:

This is not applicable because your doctor will administer this medicine.

If treatment with Phenobarbital Injection is stopped:

Stopping treatment with this medicine may result in the return and increase in seizures.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Phenobarbital Injection can cause side effects, although not everybody gets them.

Very rarely potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).

This injection may also cause:

- Breathing difficulty
- Confusion
- Loss of control of intentional movements
- Drowsiness
- Depression
- Blood disorders
- Memory impairment
- Rapid involuntary movements of the eye (Nystagmus)
- Skin reactions (though these are rare)
- Sluggishness

- Excitement and irritability
- Allergic skin reactions
- Shaky movements and unsteady walk (ataxia)
- Inflammation of the liver (hepatitis)
- Softening of bones

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.

If any of the side effects get serious, or you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

5. How to store Phenobarbital Injection

Keep out of the reach and sight of children.

Phenobarbital Injection should be kept in the outer carton in order to protect from light.

Do not use Phenobarbital Injection after the expiry date which is stated on the vial label. The expiry date refers to the last day of that month. The doctor or nurse will check that the product has not passed this date.

This medicine should not be used if it shows visible signs of deterioration. Your doctor or nurse will check this before giving this medicine to you.

This medicine is for single use only. Any remaining solution will be disposed of by your doctor or nurse.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Phenobarbital Injection contains

The active ingredient is Phenobarbital Sodium. This is the new name for Phenobarbitone Sodium. The ingredient itself has not changed.

Phenobarbital Injection is a sterile solution.

Each ml contains 15mg of Phenobarbital Sodium or

Each ml contains 30mg of Phenobarbital Sodium or

Each ml contains 60mg of Phenobarbital Sodium or

Each ml contains 200mg of Phenobarbital Sodium

The other ingredients are Propylene Glycol, Disodium Edetate and Water for Injection.

What Phenobarbital Injection looks like and contents of the pack:

Phenobarbital Injection is a clear colourless solution supplied in clear glass vials.

Each vial will contain 1ml of Phenobarbital Injection.

The medicine is supplied to your pharmacist or doctor in packs of 10 clear glass vials.

Not all strengths may be marketed.

Marketing Authorisation Holder and Manufacturer:

Martindale Pharmaceuticals, Bampton Road, Harold Hill,
Romford, RM3 8UG, United Kingdom.

Product Licence Number:

Phenobarbital Injection 15mg/ml PL 1883/6161; PA/361/5/1

Phenobarbital Injection 30mg/ml PL 1883/6188; PA/361/5/2

Phenobarbital Injection 60mg/ml PL 1883/6189; PA/361/5/3

Phenobarbital Injection 200mg/ml PL 1883/6190; HK 45682

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