

**1.4.3. PATIENT INFORMATION LEAFLET (PIL)**

**VERBITAL  
Phenobarbital Sodium Injection BP 100mg/ml-2ml**

**Read all of this leaflet carefully before you is given 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, please ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet?**

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

**2. What you need to know before you are given**

**Phenobarbital Injection**

**You should not be given 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.

**If you develop a rash or the following skin symptoms, seek**

**Immediate advice from a doctor and tell him that you are**

**Taking this medicine:**

- 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 for occurrence of serious skin reactions is within the first weeks of treatment.
- If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Phenobarbital Injection you must not be re-started on Phenobarbital Injection at any time.

### **Warnings and precautions**

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

### **Other medicines and Phenobarbital Injection**

DO NOT use Phenobarbital in combination with

- The herbal remedy St John's Wort (*Hypericum perforatum*). If you already take St John's Wort, talk to your doctor before stopping the St John's Wort preparation
- Tell your doctor if you are taking, have recently taken or might
- Take any other medicines including:
- Anticoagulants, such as warfarin (used to stop the blood clotting)
- Digitoxin, eplerenone (used to treat some heart conditions), disopyramide or quinidine (used to treat an abnormal heartbeat)

- Drugs used to treat heart problems such as metoprolol, timolol and propranolol; calcium channel blockers, such as felodipine, isradipine, nicardipine, diltiazem, verapamil, nimodipine or nifedipine
- Medicines used to treat infections, such as chloramphenicol, telithromycin, itraconazole, posaconazole, voriconazole, griseofulvin, doxycycline, metronidazole, rifampicin, indinavir, lopinavir, nelfinavir or saquinavir
- Corticosteroids, such as hydrocortisone, cortisone or prednisolone
- Cyclosporine (an immunosuppressant used following an organ transplant)
- Tropisetron and aprepitant (used to stop you feeling and being sick following chemotherapy), irinotecan (used to treat cancer), toremifene (used to treat breast cancer)
- Tibolone (used to treat osteoporosis), or gestrinone (used to treat endometriosis)
- Liothyronine or levothyroxine (used to treat an under-active thyroid gland)
- Phenytoin, sodium valproate, clonazepam, carbamazepine, vigabatrin tiagabine, ethosuximide, oxcarbazepine or lamotrigine (used to treat epilepsy)
- Theophylline (used to treat asthma, bronchitis and Emphysema), montelukast (used to prevent asthma)
- The non-steroidal anti-inflammatory drug phenylbutazone (used to treat spondylitis)
- Oral contraceptives (the Pill)
- Drugs to treat depression, such as mianserin, paroxetine, amitriptyline, moclobemide or dosulepin
- Any drugs to treat a mental health problem, such as chlorpromazine, aripiprazole, thioridazine or haloperidol
- Methadone (used as a painkiller); memantine (to treat dementia)
- Methylphenidate to treat attention deficit disorder
- Vitamin D or folic acid, your doctor may advise you to change your daily dose
- Sodium oxybate – used to treat day-time sleepiness

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

**Phenobarbital Injection and alcohol:**

You are advised NOT to drink alcohol with this medicine.

**Pregnancy, Contraception in women, breast-feeding**

**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 that your epilepsy is well controlled.
- Taking Phenobarbital during pregnancy increases the chance that the baby may have a physical birth abnormality.
- Studies with women treated with phenobarbital for epilepsy have shown that around 6-7 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 phenobarbital include heart defects and, less commonly, Cleft lip and palate defects.
- Studies have found that the risk of physical birth abnormalities increases with increasing dose of Phenobarbital. Therefore, your doctor will prescribe you the Lowest effective dose.
- 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 Phenobarbital dose when you take folic acid. This is because folic acid supplements may affect your blood levels of Phenobarbital. Some studies
- Observed that taking Phenobarbital during pregnancy increases the chance that the baby may have problems affecting learning and thinking abilities.
- Studies have also shown that babies born to mothers who have taken phenobarbital are born of smaller size than expected compared to children of mothers who did not take phenobarbital.

**Driving and using machines:**

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

**Phenobarbital Injection contains propylene glycol**

Each dose may contain up to 0.9mg of propylene glycol per ml of the undiluted product. This can be harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children less than 5 years of age and high-risk groups, such as patients with liver or kidney disease.

**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 into a muscle, under the skin or, into a vein following dilution with water
- Repeated, if necessary after 6 hours

**Use in children**

- Use with caution
- 3 - 5mg per kg body weight as a single dose into the muscle

Your doctor will advise you on the duration of your therapy.

**If you are given too much Phenobarbital Injection:**

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

- Feeling sleepy
- Feeling faint
- Feeling 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 of, 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.

If the following happens seek urgent medical advice by contacting your doctor immediately or go to the casualty department at your nearest hospital:

- An allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- A syndrome called antiepileptic hypersensitivity syndrome. Symptoms of this include fever, rash, yellowing of the eyes and skin (hepatitis), and swollen glands
- potential life-threatening skin rashes (Stevens- Johnsonsyndrome, toxic epidermal necrolysis) have been reported (see section 2) very rarely.

These are very serious but rare side effects. You may need urgent medical attention or hospitalization.

### **Other side effects**

The following side effects have been reported:

- Drowsiness, lethargy and depression
- Problems with memory and general perception in the elderly. Lack of co-ordination and clumsiness
- Involuntary movements of your eyes
- Problems with your breathing, low blood pressure
- anemia, a reduction in red blood cells characterized by headaches, weight loss and a sore mouth and tongue
- Restlessness, confusion and excitability
- Hyperactivity and behavioral problems in children
- Hepatitis (inflammation of the liver)
- Jaundice (a yellowing of the skin and whites of the eyes)
- Softening and weakening of the bones
- A severe skin reaction may occur, which may cause scaly, itchy skin, or red, itchy spots, loss of hair and nails
- 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 used for extended periods, Phenobarbital can become addictive. If you have any concerns about this, you should discuss them with your doctor. 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 sight and reach of children. Store at a temperature not exceeding 30°C, Protect from light.

### **6. Contents of the pack and other information**

#### **What Phenobarbital Injection contains**

The active ingredient is Phenobarbital Sodium. Phenobarbital Injection is a sterile solution.

The other ingredients are:

Benzyl alcohol

Ethyl alcohol

Propylene Glycol

Polyethylene Glycol-400

Water for injection.

#### **What Phenobarbital Injection looks like and contents of the pack:**

A clear colourless viscous solution filled in 2 ml clear, glass ampoules.

Carton pack:

#### **2ml**

10 x 2 ml clear colour USP Type-1 clear glass black ring ampoules loaded on a plastic tray.

10 x 2 ml tray loaded clear USP Type-1 clear glass black ring ampoules in an inner printed carton.

10 x 10 x 2 ml clear USP Type-1 clear glass black ring ampoules in an outer printed carton.

**Shelf life:** 24 months.

### **MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES**

#### **Marketing Authorisation Holder**

Verve Human Care Laboratories

15-A, Pharmacy,

Selaqui, Dehradun-248011

India

**Manufacturing Site:**

Verve Human Care Laboratories

15-A, Pharmacy,

Selaqui, Dehradun-248011



VERVE

*Human Care Laboratories.*