

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**



**Phenobarbital Sodium Injection USP<sup>®</sup>**  
Phenobarbital Sodium

Read this carefully before you or your child start taking Phenobarbital Sodium Injection USP and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your or your child's medical condition and treatment and ask if there is any new information about Phenobarbital Sodium Injection USP.

**Serious Warnings and Precautions**

**Cardiovascular Risk**

- **You will receive Phenobarbital Sodium Injection USP through injection into the vein or muscle. If your doctor injects this medication into the vein too fast, your blood pressure may drop quickly, and you may experience irregular heartbeat. This can be serious. Therefore, your doctor should observe you closely while you are receiving Phenobarbital Sodium Injection USP and after.**

**What is Phenobarbital Sodium Injection USP used for?**

- Phenobarbital Sodium Injection USP is used to treat seizures that affect part of the brain or spread to the whole brain (generalized tonic-clonic and complex partial seizures), and to induce sleep.

**How does Phenobarbital Sodium Injection USP work?**

It is not completely known how phenobarbital works.

**What are the ingredients in Phenobarbital Sodium Injection USP?**

Medicinal ingredients: phenobarbital sodium

Non-medicinal ingredients: benzyl alcohol (as a preservative), propylene glycol, hydrochloric acid (to adjust pH), water for injection.

**Phenobarbital Sodium Injection USP comes in the following dosage forms:**

Solution for injection; 30 mg phenobarbital sodium/mL and 120 mg phenobarbital sodium/mL.

**Do not use Phenobarbital Sodium Injection USP if you or your child:**

- is allergic to the active ingredient, phenobarbital, or any of the other ingredients, or to barbituric acid derivatives
- have the following symptom or problems:
  - Porphyria (a genetic disorder that can cause nervous system, blood, and skin problems).

- Lung problems or severe respiratory depression
- Liver or kidney problem
- Pauses in breathing during sleep
- Suicidal potential
- Alcohol addiction
- Drug addiction
- Uncontrolled pain

Phenobarbital sodium injection USP is not for use in the newborn.

**To help avoid side effects and ensure proper use, talk to your healthcare professional about any health conditions or problems you or your child may have BEFORE taking Phenobarbital Sodium Injection USP, including if you or your child:**

- Have ever had a rash or unusual reaction while taking phenobarbital sodium or any other antiepileptic drug.
- Have kidney or liver problems. Your doctor may need to adjust the dose.
- Drink alcohol. Drinking alcohol with phenobarbital products may make you less alert and may make feelings of anger, confusion or sadness worse.
- Are pregnant or planning to become pregnant. You must only take Phenobarbital Sodium Injection USP during pregnancy if your doctor tells you to.
  - If you become pregnant while taking Phenobarbital Sodium Injection USP, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>.
- Are nursing or plan to nurse your baby. Nursing while you are taking Phenobarbital Sodium Injection USP is not recommended.
- Are taking birth control.
  - Phenobarbital Sodium Injection USP may make hormonal birth control such as “the pill” less effective.
  - Use other forms of safe and effective birth control when taking Phenobarbital Sodium Injection USP
  - You need to use other forms of birth control until the end of your menstrual cycle after stopping treatment.
- Have used or abused drugs in the past.
- Have any of the following diseases or conditions:
  - suffer from seizures that spread to the whole brain.
  - heart problems
  - have kidney or liver problems. Your doctor may need to adjust the dose
  - hypothyroidism (a condition in which your body has low thyroid hormone)
  - myasthenia Gravis (a chronic disease that causes severe muscle weakness)
  - central nervous system depression
  - low blood pressure
  - severe anemia (low red blood cell count)

- hemorrhagic shock (shock due to bleeding)
- asthma (wheeze or gasp for air due to spasm of the airway)
- diabetes mellitus
- hyperkinesia tendencies (abnormally heightened, sometimes uncontrollable muscle movement)

**Other warnings you should know about:**

- If you use Phenobarbital Sodium Injection USP regularly for a long time, it may cause mental and physical dependence.
- Sudden removal of this drug may cause unwanted side effects. Your doctor should discontinue your drug slowly and carefully.
- Ask your doctor about signs and symptoms of life threatening skin reactions such as Stevens Johnson Syndrome (SJS; a skin reaction with rash and blisters) and Toxic Epidermal Necrolysis (TEN; a skin rash often with blisters, lesions and lifting skin) that have been reported during phenobarbital treatment. Closely monitor for skin reactions. Most often, SJS or TEN happen in the first weeks of treatment. If symptoms or signs of SJS or TEN are present, phenobarbital treatment should be stopped and you should seek urgent medical help. The best results in managing SJS and TEN come from early detection and stopping the drug treatment right away (see table of Serious Side Effects and What to do About Them, below).

**DURING treatment with Phenobarbital Sodium Injection USP, tell your doctor if you or your child develops:**

- Thoughts of suicide or self-harm
- Abnormal vision (blurry or double vision)
- Pale, blue or purple coloration of the extremity and patchy discoloration of the skin, any complaint of pain in the limb

**Driving and using machines:**

Before doing tasks that require special attention, wait until you know how you respond to Phenobarbital Sodium Injection USP. Being dizzy or drowsy can occur. Be careful to avoid accidental injury or falls.

**Tell your healthcare professional about all the medicines you or your child are taking, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Phenobarbital Sodium Injection USP:**

- Birth control pills
- Other anti-seizure drugs including phenytoin, valproic acid, carbamazepine
- Oral coumarin anticoagulants
- Antidepressants, MAO Inhibitors (e.g. isocarboxazid, moclobemide, or linezolid etc.)
- Tricyclic antidepressants (e.g. clomipramine, imipramine, or nortriptyline, amitriptyline)
- CNS depressants, including alcohol, benzodiazepines
- Corticosteroids (e.g. beclomethasone, fluticasone furoate etc.)
- Griseofulvin (an antifungal drug)

- Digitoxin
- Doxycycline (an antibiotic)
- Ketamine
- Anesthetics
- To a lesser extent: acetaminophen, estrogens, digitalis, digitoxin, cyclophosphamide, doxycycline, quinidine, and vitamin D.

**How to take Phenobarbital Sodium Injection USP:**

- This medication is an injection. It should be given to you by your doctor to stop a seizure.
- **If you are taking this medication to control your seizures, do not stop Phenobarbital Sodium Injection USP without talking to your doctor.** Stopping a seizure medicine suddenly can cause serious problems, including seizures that will not stop. Your doctor will tell you if and when you or your child can stop taking this medicine.
- When given for minor seizures, the risk of discontinuing medication prior to or during pregnancy should be weighed against the risk of congenital defects in the particular case and with the particular family history.

Pentobarbital sodium injection is not for use in newborns.

**Usual dose:**

**Preoperative**

For intramuscular or slow intravenous injection.

**Adults (≥18 years):**

100 mg to 200 mg 60 to 90 minutes prior to surgery.

**Children: (<18 years):**

1 mg to 3 mg/kg 60 to 90 minutes prior to surgery.

**Anticonvulsant**

For intramuscular or slow intravenous injection.

**Adults (≥18 years):**

100 to 320 mg IV with additional doses if necessary to a maximum daily dose of 600 mg.

**Children: (<18 years):**

Initial Loading Dose: 10-20 mg/day, maximum 125 mg/m<sup>2</sup> daily.

Maintenance Dose: 1 to 6 mg/kg/day.

**Status Epilepticus**

For slow intravenous injection.

**Adults (≥18 years):**

20 mg/kg IV at a rate of 50 mg/min.

**Children: (<18 years):**

20 mg/kg IV over 20 minutes.

**Overdose:**

If you think you have taken too much Phenobarbital Sodium USP, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

Your healthcare professional will ensure that this product is administered as it should be and that doses are not missed.

**What are possible side effects from using Phenobarbital Sodium Injection USP?**

These are not all the possible side effects you may feel when taking Phenobarbital Sodium Injection USP. If you or your child experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

The most common side effects associated with the use of Phenobarbital Sodium Injection USP are:

- Sleepiness/drowsiness, feeling tired/fatigue
- Headache, dizziness along with the feeling of a spinning movement
- Nausea/vomiting
- Broken sleep
- Depression
- Diarrhea, constipation
- Unusual or unexpected feeling of joy, happiness, excitement and confusion
- Hypotension (low blood pressure)
- Hyperactivity in children
- "Hangover" confusion especially in the elderly (drowsiness the day after a dose)

Other possible side effects associated with the use of Phenobarbital sodium injection USP:

- Increased or worsening of pre-existing pain
- Epigastric pain (pain in the upper abdomen)

<b>Serious Side Effects and What to do About Them</b>				
<b>Symptom / effect</b>		<b>Talk to your Healthcare Professional</b>		<b>Get Immediate Medical Help</b>
		<b>Only if Severe</b>	<b>In all Cases</b>	
<b>Common</b>	Low sodium level in blood (symptoms like lack of energy, confusion, muscular twitching or convulsions)		X	

**Serious Side Effects and What to do About Them**

Symptom / effect	Talk to your Healthcare Professional		Get Immediate Medical Help
	Only if Severe	In all Cases	
Nervous system problems (symptoms like dizziness, trouble walking or with coordination, feeling sleepy and tired, trouble concentrating, blurred vision, double vision, etc.)		X	
Allergies (symptoms like fever, rash and swollen lymph nodes, and may be associated with symptoms involving other organs, e.g., liver)			X
<b>Uncommon</b> Liver problems (symptoms like yellowing of your skin or the whites of your eyes, nausea or vomiting, loss of appetite, stomach pain, dark [brownish] urine etc.)		X	
Thoughts of suicide or self harm			X
Respiratory depression (shallow slow, weak breathing)			X

<b>Serious Side Effects and What to do About Them</b>			
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Thinning of the bone, bone softening, bone disease, or fractures (In situations where healthy people would not normally break a bone you may have sudden pain in any location and especially in the wrist, spine or hip. This may be a fracture.)		X	
Altered numbers and types of blood cells, symptoms like unexplained tiredness, weakness, shortness of breath, and sometimes, feeling like you are going to pass out and increased bruising, nosebleeds, sore throats, or infections)		X You should tell your doctor who may want to perform a blood test	
<b>Rare</b> Severe allergic reactions (symptoms like swelling of face, eyes, lips, or tongue, trouble swallowing or breathing, skin rash)			X

<b>Serious Side Effects and What to do About Them</b>			
<b>Symptom / effect</b>	<b>Talk to your Healthcare Professional</b>		<b>Get Immediate Medical Help</b>
	<b>Only if Severe</b>	<b>In all Cases</b>	
A rare, serious disorder in which your skin reacts severely to a medication (Stevens Johnson Syndrome; SJS). If symptoms or signs of SJS (e.g. skin rash often with blisters or lesions) are present, phenobarbital treatment should be stopped right away.			X
Severe skin reaction where the upper surface of your skin detaches like a patient who has suffered burns (Toxic Epidermal Necrolysis [TEN]). If symptoms or signs of TEN (e.g. skin rash often with blisters or mucosal lesions and lifting skin) are present, phenobarbital treatment should be stopped right away.			X

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### **3 ways to report:**

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to: 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 0701E  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store between 15°C and 25°C. Protect from freezing. Protect from light. Do not use if precipitate present.

Keep out of reach and sight of children.

### **If you want more information about Phenobarbital Sodium Injection USP:**

- Talk to your healthcare professional
- Find the full Prescribing Information that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>) or, by calling the manufacturer at 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

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