



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR,  
PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Mr C Mukaratirwa  
Cospharm Investments (Pty) Ltd  
2 Concourse Crescent  
Lonehill  
Johannesburg

Dear Mr Mukaratirwa

#### Section 21 Authorization for PHENOBARBITONE 200MG/ML INJ 1ML

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Phenobarbitone 200mg/mL Injection 1mL**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7<sup>th</sup> of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.

Department of Health • Lefapha la Pholo • Lefapha la Bophelo • uMnyango wezeMpilo • Muhasho wa Mutakalo • Departement van Gesondheid • Kgoro ya Maphelo • Ndzawulo ya Rihanyo • LiTiko le Thempilo • ISebe lezeMpilo • UmNyango WezamaPhilo

**Batho Pele - putting people first**

10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **08 May 2026**.

**Table 1: Provincial estimates**

| Province              | Six Months Estimate |
|-----------------------|---------------------|
| Correctional Services | 0                   |
| EC-MT                 | 600                 |
| EC-PE                 | 3600                |
| FS                    | 360                 |
| GP                    | 720                 |
| KZN                   | 3000                |
| LP                    | 1830                |
| MP                    | 260                 |
| NC                    | 700                 |
| NW                    | 2225                |
| SAMHS                 | 50                  |
| WC                    | 1600                |
| Total                 | 14 945              |

Yours sincerely

  
**KHADIJA JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**  
**DATE:** 11/11/2025

## Section 21 Outcome Letter

2025-11-08

Ms Buhle Mbongo

1112 Voortrekker Road

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Buhle Mbongo

### **REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND CONTROLLED SUBSTANCES ACT, 1965 (ACT 101 of 1965):**

Your application dated **2025-11-06** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: Cospharm Investments (Pty) Ltd**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 15000**
- E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**
- F. TRADE NAME: Phenobarbital Sodium BP 20 mg/L**
- G. QUANTITY: 15000 Packs (1 )**

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**H. LETTER NUMBER: S2100015402**

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

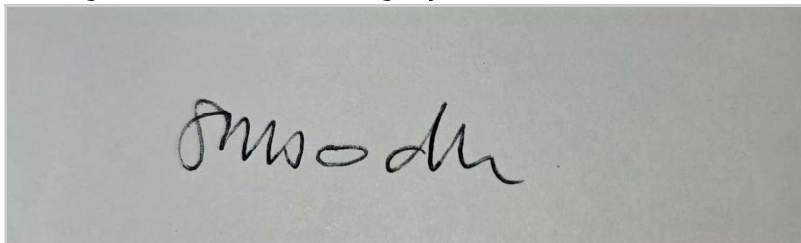
A progress report must be submitted once treatment is completed or on a reauthorization request

**Comments:**

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'Ms Moropa' written in a cursive style.

Ms Mahlodi Moropa

Final Approver

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S2100015402



SAHPRA Head Office  
Building A, Loftus Park  
2nd Floor  
Kirkness Str  
Arcadia  
0083

A rectangular box containing a handwritten signature in dark ink. The signature is stylized and appears to be a cursive or semi-cursive script, possibly reading 'M. P. P.' or similar. The background of the box is a light, neutral color.



QUQUOTATION

Date 2025/10/09  
VAT Reg No.: 4640290963  
Reg no: 2018/488705/07  
Quote No. DOH001  
Reference: BUHLE

FROM: COSPHARM INVESTMENTS (PTY)LTD  
2 Concourse Crescent  
Lonehill  
Johannesburg  
010 110 9348

TO: DEPARTMENT OF HEALTH  
Dr AB Xuma Building 1112, Voortrekker Road  
Pretoria Townlands 315 JR  
Pretoria, 0187  
012 395 8000

BANKING DETAILS  
COSPHARM INVESTMENTS (PTY) LTD  
FNB  
Account Number: 62850218241  
Branch Code: 254605  
Branch: Sandton City

| Item Code | Item Description                      | Quantity | Disc % | Price excl | Price incl | Total (Incl) |
|-----------|---------------------------------------|----------|--------|------------|------------|--------------|
| PHEN200   | PHENOBARBITONE 200MG/ML INJECTION 1ML | 15000    | 0      | 11,76      | R 13,52    | R 202,800,00 |

Validity Period: 90 Days  
Lead Times: 4 weeks after receipt of a formal Purchase Order  
Country of origin India  
Manufacturer Swiss Parentals

|                   |   |            |
|-------------------|---|------------|
| SubTotal (Excl)   | R | 172,380,00 |
| VAT Total at 15%  |   | 30,420,00  |
| Invoice Total ZAR | R | 202,800,00 |

Signature:





2 Concourse Crescent, Lonehill,  
Johannesburg 2191 Gauteng  
+27 10 110 9348  
info@cospharm.org

| <b>REQUEST FOR QUOTATION FORM</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                            |                                 |        |            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|---------------------------------|--------|------------|
| <ul style="list-style-type: none"> <li>• <b>Instruction to complete this Request for Quotation (RFQ)</b><br/>PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).<br/>PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.<br/>THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.</li> <li>• THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS TO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.</li> </ul> |                                                                            |                                 |        |            |
| <b>ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                            |                                 |        |            |
| REFERENCE NUMBER:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | NORMAL                                                                     | SECTION 21                      | X      | S21RFQ160  |
| QUOTE ENQUIRY DATE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 01/10/2025                                                                 | QUOTE CLOSING DATE              |        | 10/10/2025 |
| FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE<br>(SCM Practitioner to Specify if applicable)                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                            |                                 |        |            |
| <b>REQUESTING INSTITUTION CONTACT DETAILS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                            |                                 |        |            |
| NAME OF REQUESTOR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Buhle Mbongo                                                               |                                 |        |            |
| EMAIL ADDRESS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <a href="mailto:Buhle.Mbongo@health.gov.za">Buhle.Mbongo@health.gov.za</a> |                                 |        |            |
| PHONE No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 012 395 9539                                                               | FAX No.                         | N/A    |            |
| <b>PRODUCT INFORMATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                            |                                 |        |            |
| DESCRIPTION PER MPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | PHENOBARBITONE 200MG/ML INJECTION 1ML                                      |                                 |        |            |
| TRADE DESCRIPTION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                            |                                 |        |            |
| UNIT OF MEASURE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 1 vial                                                                     | PACK or BOX (SIZE/<br>QUANTITY) | 1 vial |            |
| QUANTITY REQUIRED                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 15000 vials/ampoules                                                       |                                 |        |            |
| <b>TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                            |                                 |        |            |
| <b>SUPPLIER CONTACT DETAILS (as per CSD)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                            |                                 |        |            |
| COMPANY NAME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | COSPHARM INVESTMENTS (PTY) LTD                                             |                                 |        |            |
| SUPPLIER NUMBER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | MAAA0922336                                                                |                                 |        |            |
| SECURITY CODE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                            |                                 |        |            |



www.cospharm.org





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Johannesburg 2191 Gauteng  
 +27 10 110 9348  
 info@cospharm.org

|                                   |         |                                    |            |
|-----------------------------------|---------|------------------------------------|------------|
| SUPPLIER CODE (NDoH)              | VK0P8   |                                    |            |
| CONTACT PERSON 1                  | NAME    | COSMAS MUKARATIRWA                 |            |
|                                   | PHONE   | 010 110 9348                       | FAX N/A    |
|                                   | MOBILE  | 081 310 0293                       |            |
|                                   | E-MAIL  | info@cospharm.org                  |            |
| CONTACT PERSON 2                  | NAME    | ANDISWA MAHLANGU                   |            |
|                                   | PHONE   | 010 110 9348                       |            |
|                                   | MOBILE  |                                    |            |
|                                   | E-MAIL  | marketingza@cospharm.org           |            |
| <b>QUOTE DETAILS</b>              |         |                                    |            |
| PRICE PER VIAL (INCL. VAT)        | R13.52  | TOTAL PRICE (INCL. DELIVERY & VAT) | 202 800.00 |
| *STOCK'S EXPIRY DATE(SHELF-LIFE)  | 2 YEARS |                                    |            |
| VOLUMES AVAILABLE – 7DAYS         |         |                                    |            |
| VOLUMES AVAILABLE – 14DAYS        |         |                                    |            |
| VOLUMES AVAILABLE – 21DAYS        |         |                                    |            |
| VOLUMES AVAILABLE – 28DAYS        |         |                                    |            |
| VOLUMES AVAILABLE – 35DAYS        |         |                                    |            |
| VOLUMES AVAILABLE - 42DAYS        |         |                                    |            |
| VOLUMES AVAILABLE – 49DAYS        |         |                                    |            |
| VOLUMES AVAILABLE – 56DAYS        | 15000   |                                    |            |
| VOLUMES AVAILABLE – 112DAYS       |         |                                    |            |
| QUOTE VALIDITY PERIOD             | 90 DAYS |                                    |            |
| NORMAL LEAD/DELIVERY TIME         | 4 WEEKS |                                    |            |
| <b>DEVIATION TO SPECIFICATION</b> |         |                                    |            |



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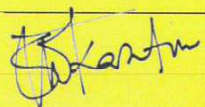


2 Concourse Crescent, Lonehill,  
Johannesburg 2191 Gauteng  
+27 10 110 9348  
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COMMENTS: AS PER SPECIFICATION

**DECLARATION BY SUPPLIER**

I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.

|                                                                       |                                                                                    |
|-----------------------------------------------------------------------|------------------------------------------------------------------------------------|
| NAME                                                                  | COSMAS MUKARATIRWA                                                                 |
| CAPACITY                                                              | CEO                                                                                |
| SIGNATURE<br>(OF A DULY AUTHORISED<br>REPRESENTATIVE OF THE SUPPLIER) |  |
| DATE                                                                  | 09/10/2025                                                                         |

Please submit quotations to [Section21Quotes@health.gov.za](mailto:Section21Quotes@health.gov.za)



[www.cospharm.org](http://www.cospharm.org)

Prescription only medicine

# Phenobarbital Injection BP 200 mg/ml

(For IM or Slow IV Use)

## COMPOSITION :

Each ml contains :  
Phenobarbital Sodium BP...200 mg  
Water for Injections BP.....q.s.

## CHEMISTRY:



**THERAPEUTIC CLASSIFICATION:** NSAID (Anticonvulsant)

## DESCRIPTION:

**Chemical Name:** Phenobarbital sodium is 2,4,6-(1H,3H,5H)-Pyrimidine-2,4,6-trione, 5-ethyl-5-phenyl-, monosodium salt.

**PHARMACOLOGY PROPERTIES:** Barbiturates are capable of producing all levels of CNS mood alteration from excitation to mild sedation, to hypnosis and deep coma. Overdosage can produce death. In high enough therapeutic doses, barbiturates induce anesthesia. Barbiturates depress the sensory cortex, decrease motor activity, alter cerebellar function and produce drowsiness, sedation and hypnosis. Barbiturates have little analgesic action at sub anesthetic doses. Rather, in sub anesthetic doses these drugs may increase the reaction to painful stimuli. All barbiturates exhibit anticonvulsant activity in anesthetic doses. Barbiturates are respiratory depressants by virtue of their direct effect on the medullary respiratory center. They diminish and, in high doses, may abolish the sensitivity of the respiratory center to its normal stimulus, carbon dioxide. Ordinary hypnotic doses of barbiturates have no significant effect on the cardiovascular system. The barbiturates tend to decrease the tone of the gastrointestinal musculature. They have no direct injurious effect on the normal kidney. Hypnotic doses tend to reduce slightly the metabolic rate in man. Body temperature is reduced slightly, owing to lessened activity and to depression of the central temperature-regulatory mechanisms.

**PHARMACOKINETIC PROPERTIES :** Following IV administration, the onset of action is 5 minutes for phenobarbital sodium. For IM administration, the onset of action is slightly slower. Maximal CNS depression may not occur until 15 minutes or more after IV administration. Duration of action, which is related to the rate at which the barbiturates are redistributed throughout the body, varies among persons and in the same person from time to time. No studies have demonstrated that the different routes of administration are equivalent with respect to bioavailability. Barbiturates are weak acids that are absorbed and rapidly distributed to all tissues and fluids with high concentrations in the brain, liver and kidneys. Lipid solubility of the barbiturates is the dominant factor in their distribution within the body. The more lipid soluble the barbiturate, the more rapidly it penetrates all tissues of the body. Barbiturates are bound to plasma and tissue proteins to a varying degree with the degree of binding increasing directly as a function of lipid solubility. Phenobarbital has the lowest lipid solubility, lowest plasma binding, lowest brain protein binding, the longest delay in onset of activity and the longest duration of action. Its diffusion across the blood-brain barrier and its distribution into other tissues occurs more slowly than with other short-acting barbiturates. Fifteen minutes or more may be required for maximal central depression following intravenous administration of Phenobarbital. However, with time, Phenobarbital distributes into all tissues and fluids. Barbiturates are known to cross the placenta. Phenobarbital is 20-45% protein bound. In adults, the plasma half-life of Phenobarbital is 53 to 118 hours (mean 79 hours) and in children/newborns, the plasma half-life is 60 to 180 hours (mean 110 hours). Barbiturates are metabolized primarily by the hepatic microsomal enzyme system, and the metabolic products are excreted in the urine and, less commonly, in the feces. Approximately 25 to 50 percent of a dose of Phenobarbital is eliminated unchanged in the urine, whereas the amount of other barbiturates excreted unchanged in the urine is negligible. Urinary pH and rate of urine flow affect the renal circulation of unchanged Phenobarbital, a greater quantity being eliminated in alkaline urine and at increased flow rates. The excretion of unmetabolized barbiturate is one feature that distinguishes the long-acting category from those belonging to other categories which are almost entirely metabolized. The inactive metabolites of the barbiturates are excreted as conjugates of glucuronic acid.

**INDICATIONS :** sedative action of this class of drugs is desired are anxiety-tension states, hyperthyroidism, essential hypertension, nausea and vomiting of functional origin, motion sickness, acute labyrinthitis, pylorospasm in infants, chorea and cardiac failure. Phenobarbital is also a useful adjunct in treatment of hemorrhage from the respiratory or gastrointestinal tract. Phenobarbital controls anxiety, decreases muscular activity and lessens nervous excitability in hyperthyroid patients. However, thyrotoxic individuals occasionally react poorly to barbiturates. Long-term anticonvulsant. (Phenobarbital, mephobarbital and metharbital) for the treatment of generalized tonic-clonic and cortical focal seizures. And, in the emergency control of certain acute convulsive episodes, e.g., those associated with status epilepticus, cholera, eclampsia, cerebral hemorrhage, meningitis, tetanus, and toxic reactions to strychnine or local anesthetics.

## RECOMMENDED DOSE:

### 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

### Children :

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

**ROUTE OF ADMINISTRATION :** Intramuscular/Slow Intravenous

**CONTRAINDICATIONS :** Barbiturates are contraindicated in patients with known barbiturate sensitivity. Barbiturates are also contraindicated in patients with a history of manifest or latent porphyria, marked impairment of liver functions or with severe respiratory distress where dyspnea or obstruction is evident. Large doses are contraindicated in nephritic subjects. Barbiturates should not be administered to persons with known previous addiction to the sedative-hypnotic group since ordinary doses may be ineffectual and may contribute to further addiction. Intra-arterial administration is contraindicated. Its consequences vary from transient pain to gangrene. Subcutaneous administration produces tissue irritation, ranging from tenderness and redness to necrosis and is not recommended.

**WARNINGS AND PRECAUTIONS :** Phenobarbital Sodium Injection contains the preservative benzyl alcohol and is not recommended for use in neonates. There have been reports of fatal 'gassing syndrome' in neonates (children less than one month of age) following the administration of intravenous solutions containing the preservative benzyl alcohol. Symptoms include a striking onset of gasping respiration, hypotension, bradycardia, and cardiovascular collapse.

### Dermatologic Reactions

Exfoliative dermatitis and Stevens-Johnson syndrome, possibly fatal, are rare hypersensitivity reactions to Phenobarbital.

### Intravenous Administration

Too rapid administration may cause severe respiratory depression, apnea, laryngospasm, hypertension or vasodilatation with fall in blood pressure..

### Acute or Chronic Pain

Caution should be exercised when barbiturates are administered to patients with acute or chronic pain, because paradoxical excitement could be induced or important symptoms could be masked.

## Use in Pregnancy

Barbiturates can cause fetal harm when administered to a pregnant woman. Retrospective, case-controlled studies have suggested a connection between the maternal consumption of barbiturates and a higher than expected incidence of fetal abnormalities. Phenobarbital may cause major fetal malformations.

## Use in Children

Phenobarbital has been reported to be associated with cognitive defects in children taking it for complicated febrile seizures.

## Precaution :

### General

Untoward reactions may occur in the presence of fever, hyperthyroidism, diabetes mellitus and severe anemia.

## INTERACTION WITH OTHER MEDICINAL :

### Anticoagulants

Phenobarbital lowers the plasma levels of dicumarol (bishydroxycoumarin) and causes a decrease in anticoagulant activity as measured by the prothrombin time. Barbiturates can induce hepatic microsomal enzymes resulting in increased metabolism and decreased anticoagulant response of oral anticoagulants

### Corticosteroids

Barbiturates appear to enhance the metabolism of exogenous corticosteroids probably through the induction of hepatic microsomal enzymes.

### Griseofulvin

Phenobarbital appears to interfere with the absorption of orally administered griseofulvin, thus decreasing its blood level.

### Doxycycline

Phenobarbital has been shown to shorten the half-life of doxycycline for as long as 2 weeks after barbiturate therapy is discontinued.

### Phenytoin, Sodium Valproate, Valproic Acid

The effect of barbiturates on the metabolism of phenytoin appears to be variable. Some investigators report an accelerating effect, while others report no effect.

### Central Nervous System Depressants

The concomitant use of other central nervous system depressants, including other sedatives or hypnotics, antihistamines, tranquilizers or alcohol, may produce additive depressant effects.

### Monoamine Oxidase Inhibitors (MAOIs)

MAOIs prolong the effects of barbiturates probably because metabolism of the barbiturate is inhibited.

### Estradiol, Estrone, Progesterone and Other Steroidal Hormones

Pretreatment with or concurrent administration of Phenobarbital may decrease the effect of estradiol by increasing its metabolism.

## PREGNANCY AND LACTATION :

### Use in pregnancy:

#### Teratogenic Effects-Pregnancy Category D

Phenobarbital may cause major fetal malformations. (See WARNINGS, Use in Pregnancy.)

#### Nonteratogenic Effects

Reports of infants suffering from long-term barbiturate exposure in utero included the acute withdrawal syndrome of seizures and hyperirritability from birth to a delayed onset of up to 14 days

**Nursing mothers:** Caution should be exercised when a barbiturate is administered to a nursing woman since small amounts of barbiturates are excreted in the milk.

## UNDESIRABLE ACTION :

### Nervous System

Somnolence, agitation, confusion, hyperkinesia, ataxia, CNS depression, nightmares, nervousness, psychiatric disturbance, hallucinations, insomnia, anxiety, dizziness, thinking abnormally

### Respiratory System

Hypoventilation, apnea

### Cardiovascular System

Bradycardia, hypotension, syncope

### Digestive System

Nausea, vomiting, constipation

### Dermatologic Reactions

Exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidemic necrolysis.

**OVERDOSAGE AND THERAPEUTIC MEASUREMENT :** For sedation, therapeutic blood levels of Phenobarbital range from 5-40 µg/mL; the lethal blood level is greater than 80 µg/mL and usually ranges from 100-200 µg/mL. Acute overdosage with barbiturates is manifested by CNS and respiratory depression which may progress to Cheyne-Stokes respiration, areflexia, constriction of the pupils to a slight degree (though in severe poisoning, they may show paralytic dilation), oliguria, tachycardia, hypotension, lowered body temperature and coma. Typical shock syndrome (apnea, circulatory collapse, respiratory arrest and death) may occur. In extreme overdose, all electrical activity in the brain may cease, in which case a "flat" EEG normally equated with clinical death cannot be accepted. This effect is fully reversible unless hypoxic damage occurs. Consideration should be given to the possibility of barbiturate intoxication even in situations that appear to involve trauma. Complications such as pneumonia, pulmonary edema, cardiac arrhythmias, congestive heart failure and renal failure may occur. Uremia may increase CNS sensitivity to barbiturates if renal function is impaired. Differential diagnosis should include hypoglycemia, head trauma, cerebrovascular accidents, convulsive states and diabetic coma. To obtain up-to-date information about the treatment of overdosage, a good resource is your certified Regional Poison Control Center. Telephone numbers of certified poison control centers are listed in the Physicians' Desk Reference (PDR). In managing overdosage, consider the possibility of multiple drug overdose, interaction among drugs and the unusual drug kinetics in your patient.

Treatment of overdosage is mainly supportive and consists of the following:

Maintenance of an adequate airway, with assisted respiration and oxygen administration as necessary.

- Monitoring of vital signs and fluid balance.
- Fluid therapy and other standard treatment for shock, if needed.
- If renal function is normal, forced diuresis may aid in the elimination of the barbiturate. Alkalinization of the urine increases renal excretion of phenobarbital.
- Although not recommended as a routine procedure, hemodialysis may be used in severe barbiturate intoxication or if the patient is anuric or in shock. Hemoperfusion through an anion-exchange resin or activated charcoal has been successful. Peritoneal dialysis is significantly less effective in removing barbiturates.
- Patient should be rolled from side to side every 30 minutes.
- Antibiotics should be given if pneumonia is suspected.
- Appropriate nursing care to prevent hypostatic pneumonia, decubiti, aspiration and other complications of patients with altered states of consciousness.
- The use of analeptic agents is not recommended.

**STORAGE CONDITION:** Store below 25°C. Protect from light.

## KEEP OUT OF REACH OF CHILDREN.

## DOSEAGE FORM AND PACKING STYLE:

**Dosage Form:** Solution for Injection

**Packing Style:** Available in glass Ampoule.

Manufactured by:

**SWISS PARENTERALS LTD.**

Ahmedabad, Gujarat, INDIA.

Phenobarbital Injection BP 200 mg/ml

Prescription Only Medicine

Phenobarbital Injection BP  
200 mg/ml

(For IM or Slow IV Use)  
Solution for Injection

10 x 1 ml Ampoule



Phenobarbital Injection BP  
200 mg/ml

**Composition :**

Each ml contains :  
Phenobarbital Sodium BP 200 mg  
Water for Injections BP q.s.

**Dosage :**

As directed by the physician.

**Storage :** Store below 25°C. Protect  
from light.

**KEEP OUT OF REACH OF  
CHILDREN.**

If given intravenously, must be  
diluted before use.

Manufactured by:

**SWISS PARENTERALS LTD.**

808, 809 & 810, Kerala Industrial Estate,  
GIDC, Nr. Bavla, Dist.: Ahmedabad-382 220,  
Gujarat, INDIA.

Mfg. Lic. No.: G/28/1078

Batch No.:

Mfg. Date:

Exp. Date:

NVZ  
48 X 14 mm

Phenobarbital Injection BP 200 mg/ml

Phenobarbital Injection BP  
200 mg/ml

Non Varnish/UV Zone For  
**2D Barcode**  
(Global Trade Item Number)  
(Compulsory)  
Size : 22 x 36 mm