

LUMINAL inj. 200mg

(Phenobarbital sodium 200mg/2mL)

■ **COMPOSITON** : Each ampoule (2mL) contains

Active ingredients per ampoule : 200mg of Phenobarbital sodium

Inactive ingredients per ampoule : Benzyl alcohol 0.04mL : Propylene glycol 1.2mL : Citric acid q.s : Water for injection q.s..

■ **INDICATION**

Sedation, Epilepsy, Epileptic status

■ **DOSAGE & ADMINISTRATION** : For adults

1. Sedation, Epilepsy

50-200 mg as phenobarbita sodium injected intramuscularly or subcutaneously a day

2. Epileptic status

200-600 mg as Phenobarbital is injected subcutaneously.

This dose may be increased or decreased according to the age and/or the symptoms.

■ **PRECAUTION**

1. Precaution

It has been reported that Benzyl-alcohol is related to respiratory depression in the Premature infants.

2. Contraindication

- 1) Patients with severe hepatic disturbances
- 2) Patients with nephritis or renal diseases
- 3) Patients with cardiac failure
- 4) Patients with respiratory diseases
- 5) Patients with acute intermittent porphyria
- 6) Patients with hypersensitivity to Barbiturates and Patients with idiosyncrasy
- 7) Patients in condition of uncontrollable pain
- 8) Patients with known habitual intoxication to hypnotic sedatives
- 9) Pregnancy, possible pregnancy or nursing mothers
- 10) Newborn, Premature infants(This drug contains Benzyl-alcohol)

3. Should be given cautiously to the following patients.

- 1) Patients with organic cerebral insufficiency
- 2) Patients with hepatic and renal disturbances
- 3) Patients with cardiac disturbances
- 4) Patients with fever
- 5) Patients with hypothyroidism
- 6) Patients with diabetes
- 7) Patients with severe anemia
- 8) Patients with shock status or uremia
- 9) The elderly or debilitated patients.
- 10) Patients in anticoagulant therapy
- 11) Patients with drug hypersensitivity
- 12) Patients with alcoholism
- 13) Patients with severe neurosis

4. Adverse reaction

- 1) Drug dependency or withdrawal syndrome : Prolonged administration may occasionally result in Psychological dependence, physical dependence. At the occurrence of withdrawal symptoms, a close medical control and support of the patient is necessary. Abrupt discontinuation should be avoided and the doses should be diminished gradually.
- 2) Skin : Skin rash may occur. Stevens-Johnson syndrome, Lyell syndrome, exfoliative dermatitis are extremely rare. In such a case, a close medical control and appropriate treatment is instituted.
- 3) Respiratory system : It has been reported that respiratory depression may occur
- 4) Blood : Occasionally thrombopenia, megaloblastic anemis, hypocalcemia, aplastic anemia etc. may occur. In case of those, a close medical control and appropriate treatment is instituted.
- 5) Liver : Occasionally, rise in AST, ALT, γ -GTP levels, jaundice, porphyria rarely, etc. may occur. Thus, should be monitored carefully. a close medical control and appropriate treatment instituted.
- 6) Neurologic : Drowsiness, lethargy, hangover, asterixis, dizziness occasionally, headache, hallucination, confusion, dullness, disturbance of verbal, impairment of concentrations, kinesioneurosis and mental hypofunction may occur. In case of those, dosage reduce and appropriate treatment instituted. Especially in the elderly, confusion or excitation may occur.
- 7) Kidney : : Renal disorder such as hematoporphyruria, proteinuria may occur
- 8) Gastrointestinal : Anorexia etc. may occur.
- 9) Hypersensitivity : When occasionally the symptoms such as erythema, morbilliform erythema, rash etc. occur, the therapy should be discontinued.
- 10) Musculoskeletal : Rickets, osteomalacia, and dentification disorder etc. may occur on account of prolonged administration. Thus, should be monitored well enough and a close medical control and appropriate treatment is instituted.
- 11) Endocrine : Disorder of hypothyroid level (serum T4) may occur.
- 12) Cardiovascular: Bradycardia, hypotension, and shock may occur. And arrhythmia in high dosage may occur.
- 13) Eye : Diplopia, nystagmus etc. may occur in high dosage and prolonged administration
- 14) Granulocytopenia : Granulocytopenia may occur. In case of those, a close medical control and appropriate treatment instituted.

15) Other : pyrexia and arthralgia may occur.

5. General precaution

- 1) Patients taking this drug should be warned against engaging in hazardous occupations requiring mental alertness such as operating a motor vehicle or other machinery since drowsiness, decrease in carefulness, concentration, motor reflex may occur.
- 2) Administered a barbiturate to patients with acute and chronic pain, paradoxical excitation may occur or cover up symptom. Thus, should be monitored carefully.
- 3) Necrosis on injection site may occur. Therefore do not administerate except oral administration inability or emergency.
- 4) Prolonged administration should be monitored function of renal and liver.

6. Drug Interaction

- 1) Combination therapy may increase drug Interaction, it should be done cautiously : CNS depressants (phenothiazine derivatives, barbiturates, tranquilizing drug), MAO inhibitors such as antidepressant, disulfiram.
- 2) Combination with ether or curare may increase respiration depression, it should be done cautiously.
- 3) Combination with anticoagulants(warfarin etc) may decrease anticoagulation action. Therefore caogulation time should be checked often and dosage should be control.
- 4) Combination with thiazide diuretic may increase orthostatic hypotension. Therefore the dosage should be reduced and done cautiously.
- 5) It has been reported that combination with adrenocortical hormone(dexamethasone etc.) may decrease adrenocortical hormone action.
- 6) Combination with this drug may decrease absorption of griseofulvin. Therefore, do not administerate combination
- 7) It has been reported that combination with theophylline decrease serum concentration of theophylline
- 8) It has been reported that combination with doxycycline have shortened a serum concentration half life of doxycycline.
- 9) Action of barbiturates against phenytoin cannot be foreseen. Therefore serum concentration of barbiturates and phenytoin should be checked often.
- 10) Combination with acetazolamide may occur rickets and osteomalacia.
- 11) Combination with valproic acid may increase serum concentration of this drug, therefore should be monitored well enough and appropriate treatment should be instituted.

7. Use in pregnancy

- 1) Significantly increased number of malformed babies(cleft palate, cleft ips etc.), from the women who have been administered during pregnancy, compared to control group, is reported as prospective following up. Therefore, it should be done cautiously
- 2) Risk of bleeding or respiratory depression may occur.
- 3) It has been reported that the prolonged administration of this drug before parturition produce withdrawal syndrome (polycoria, tremor, dysreflexia, hypertonia, etc.) in the neonates.
- 4) It has been reported that administration during pregnancy decreases folic acid.

8. Use in the elderly

When this drug administrate the elderly, respiratory depression, excitation, depression, confusion etc. may occur. Therefore the dosage should be started low dosage and done cautiously.

9. Treatment of overdosage

- 1) Symptoms : Inhibition of CNS or Cardiac may occur. When serum concentraion is over 40-45 $\mu\text{L}/\text{mL}$, Drowsiness, nystagmus, kinesioneurosis may occur. Complications such as pneumonia, pulmonary edema, cardiac arrhythmias, congestive heart failure, and renal failure may occur.
- 2) Treatment : Maintenance of an adequate airway with assisted respiration and oxygen administration as necessary. If emesis is contraindicated, gastric lavage may be performed with a cuffed endotracheal tube in place with the patient in the face down position. Activated charcoal may be left in the emptied stomach and a saline cathartic administered. If renal function is normal, forced diuresis may aid in the elimination of the barbiturate. Alkalinization of the urine increases renal excretion of some barbiturates, especially phenobarbital, also aprobarbital, and mephobarbital (which is metabolized to phenobarbital). hemodialysis may be used in severe barbiturate intoxications.

10. Precaution in application

- 1) Overdose or rapid injection produce respiratory depression and decrease of blood pressure. Injection rate should be slowly.
- 2) Avoid intra-arterial injection

■ **STORAGE** : Well-closed container

■ **USE TERM** : 3 Years

■ **PACKS** : 2mL X 10, 50, 100Amp.

※ **Medicine** : Keep out of reach of children.

This drug is manufactured in accordance with Korea Good Manufacturing Practice (KGMP) as recommended by WHO.
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