PACKAGE LEAFLET: Information for the patient

LUMINAL

Solution for injection – 200 mg / 2 ml (10%)

(Phenobarbital sodium)

Tablets – 15 mg, 60 mg

(Phenobarbital)

Read 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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT LUMINAL IS AND WHAT IT IS USED FOR

Luminal contains as active substance phenobarbital, which is part of the group of barbiturates. It may affect the brain activity at different levels, from excitation to mild sedation to hypnosis and coma. High therapeutic doses of barbiturates may produce anesthesia. Overdoses may cause death. Phenobarbital depresses the sensory cortex, decreases motor activity, alters cerebellar function and causes drowsiness, sedation and hypnosis. Barbiturates have poor analgesic activity

in subanesthetic doses and may increase the response to painful stimuli. All barbiturates exhibit anticonvulsant action at anesthetic doses. Barbiturates are respiratory depressants. The degree of respiratory depression is dependent upon the dose. Barbiturates are absorbed in varying degrees following oral or parenteral administration. The salts are absorbed faster than the acids. The rate of absorption is increased if sodium salts are given as a dilute solution or taken on an empty stomach. The onset of action ranges from 20 to 60 minutes after oral administration. After intramuscular injection, the onset of action is more rapid, while after intravenous administration the action may start after 5 minutes. Maximal depression of central nervous system may not occur until 15 minutes after intravenous injection.

Luminal is used:

- as long-term treatment of generalised tonic-clonic and focal-cortical seizures;
- as part of the emergency treatment of acute convulsions, including *status epilepticus*;
- as short-term treatment of insomnia;
- as preanesthetic sedation;
- in the treatment of febrile seizures in children.

2. BEFORE YOU TAKE LUMINAL

Do not take Luminal if you:

- are sensitive (allergic) to phenobarbital, other barbiturates or to any of the excipients listed at the end of this leaflet;
- have porphyria;
- have severe impaired liver function;
- have severe respiratory depression;
- suffer from nephritis or renal failure;
- have dependence to hypnotic and sedative drugs.

Luminal solution for injection should not be used in children under 3 years because it contains benzyl alcohol.

If you develop a rash or the following skin symptoms, seek immediate advice from a doctor and tell that you are taking this medicine:

- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported 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 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 Luminal, you must not re-start its use at any time.

Take special care with Luminal

Ask your doctor before you take Luminal.

Phenobarbital should be used with caution:

- in children and in elderly or debilitated patients, in those with acute pain, and in patients with depressive disorders;
- if you have impaired renal or hepatic function (should be avoided when the impairment is severe);
- if you have respiratory depression (should be avoided when the impairment is severe);
- if you have problems with drugs or alcohol abuse;
- in patients who are immobilized for long periods or who have inadequate sun exposure or dietary intake of calcium, because vitamin D supplementation may be necessary;
- in patients who are driving or using machinery;
- if you are pregnant or breast-feeding.

Avoid abrupt withdrawal of antiepileptic drugs.

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

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Luminal.
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
Do not forget to inform your doctor for the treatment with Luminal if you receive any other medicine during treatment.

Phenobarbital accelerates the metabolism, reducing the plasma concentration, of the following drugs:
methadone; anticoagulants (coumarins); antidepressants (paroxetine, mianserin, tricyclic antidepressants); telithromycin (phenobarbital reduces its plasma concentration; should be avoided during treatment and 2 weeks after taking phenobarbital); antiepileptics (carbamazepine, lamotrigine, tiagabine, zonisamide, ethosuximide); antipsychotics (haloperidol, chlorpromazine, aripiprazole etc.); anxiolytics and hypnotics (clonazepam); betablockers (metoprolol, timolol, propranolol); calcium-channel blockers (felodipine, isradipine, diltiazem, verapamil etc.); cyclosporin; corticosteroids; diuretics (eplerenone – avoid concomitant use); montelukast; oestrogens and progesterone (phenobarbital reduces their contraceptive effect); tacrolimus; theophylline; thyroid hormones; digitoxin; anti-arrhythmics (dronedarone, disopyramide) - avoid concomitant use; quinidine; rifampicin; doxycycline; chloramphenicol; metronidazole; paracetamol; caffeine; antifungals (itraconazole, posaconazole, voriconazole, griseofulvin, fluconazole, ketoconazole); antivirals; cytotoxics (etoposide); vitamins (phenobarbital increases requirements for vitamin D); aprepitant.

Plasma concentration of phenobarbital may increase by the influence of the following drugs:
antiepileptics (oxcarbazepine, phenytoin, rufinamide, stiripentol, valproate); and methylphenidate.

Plasma concentration of phenobarbital may decrease by the influence of the following drugs:
folic acid, hypericum perforatum (St. John’s wort), with the latter, concomitant administration with phenobarbital should be avoided.
This interaction list is not exhaustive. There are other drugs that may interact with Luminal.

Taking Luminal with food and drinks

You should not drink alcohol meanwhile you are being treated with Luminal because alcohol may increase the sedative effect of Luminal.

Pregnancy

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

Phenobarbital therapy in epileptic pregnant women presents a risk to the fetus in terms of major and minor congenital defects such as congenital craniofacial, digital abnormalities and, less commonly, cleft lip and palate. The risk of developing teratogenic effects appears to be greater if more than one antiepileptic drug is administered.

Luminal should be avoided during pregnancy.

Breastfeeding

Phenobarbital is excreted into breast milk and drowsiness may occur; thus it should be avoided when possible during breastfeeding.

Driving and using machines

Luminal (phenobarbital) may affect the ability of the patient to drive or use machinery.

Important information about some of the excipients of Luminal

Luminal 15 mg or 60 mg tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Luminal solution for injection contains ethyl alcohol (ethanol). Ethyl alcohol is harmful for those suffering from alcoholism. Also, special care should be taken into account in pregnant or breast-feeding women, children and high-risk groups.

Luminal solution for injection contains 30 mg / 2 ml benzyl alcohol, therefore it must not be given to premature babies or neonates. Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3 years old, thus its use should be avoided in this age group. Also, special care should be taken into account in pregnant or breastfeeding women, in

those suffering from a liver or kidney disease because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Luminal solution for injection contains propyleneglycol. Propyleneglycol may cause side effects in children less than 5 years old, in particular if they use other medicines that contain propyleneglycol or alcohol. Consult your doctor before use! Also, special care should be taken into account in pregnant or breast-feeding women and in those suffering from a liver or kidney disease. Your doctor may carry out extra checks while you are taking this medicine.

3. HOW TO TAKE LUMINAL

Always take Luminal exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you feel that the effects of Luminal are too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with at least a half glass of water. You can take the tablets with or without food.

Luminal 15 mg or 60 mg tablets:

In infants and children

- *As anticonvulsant, by mouth:* a loading dose of 15 – 20 mg / kg body weight gives blood levels at approximately 20 mcg / ml just after use.

Adults

- *As sedative:* 30 – 120 mg daily, in 2 – 3 divided doses.
- *As hypnotic:* 100 – 200 mg;
- *As anticonvulsant*: 60 – 100 mg per day.

Children:

- *As anticonvulsant*: 3 – 6 mg / kg body weight per day.
- *As sedative:* 8 – 32 mg.
- *As hypnotic:* determined by age and weight.

Luminal 200 mg / 2 ml Solution for injection

Before intravenous administration, Luminal solution for injection should be diluted.

Adults

- *As sedative:* 30 – 120 mg a day in 2 – 3 separate doses given parenterally by intramuscular or intravenous injection.
- *For sedation preoperatively:* 100 – 200 mg, only by intramuscular injection, 60 – 90 minutes before surgery.
- *As hypnotic:* 100 – 320 mg by intramuscular or intravenous injection.
- *As anticonvulsant:* 200 – 320 mg in acute cases, by intramuscular or intravenous injection repeated if necessary after 6 hours.

Children

- *For sedation preoperatively:* 1 – 3 mg / kg body weight by intramuscular or intravenous injection.
- *As anticonvulsant:* 4 – 6 mg / kg body weight per day, for 7 – 10 days until blood levels of 10 – 15 mcg / ml are achieved, or 10 – 15 mg / kg body weight per day by intramuscular or intravenous injection.
- *In status epilepticus:* 15 – 20 mg / kg body weight by intravenous injection within 10 – 15 minutes. It is important to achieve therapeutic levels as soon as possible. When it is given intravenously, 15 minutes may be needed to reach maximum levels in the brain.

If you take more Luminal than you should

If you take more Luminal than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures. If you take more Luminal than you should, the following symptoms may appear: fatigue, lethargy, nausea, vomiting, sweating, confusion, hypotension, etc.

If you forget to take Luminal

If you forget to take one dose (or more than one dose), take the next dose in its usual time.
Do not take a double dose (or higher) to make up for the forgotten dose(s).

If you stop taking Luminal

Avoid abrupt withdrawal. Reduction in dosage should be gradual.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Luminal can cause side effects, although not everybody gets them. Sometimes they are serious, most of the times not. Do not be alarmed by this list of possible side effects. You may not get any of them.

As adverse effects during the use of Luminal may be mentioned: sedation, drowsiness, agitation, confusion, hyperkinesia, ataxia, involuntary eye movements (*nystagmus*), nervous system depression, nightmares, irritability, psychiatric disorders, hallucinations, impaired memory and cognition, insomnia, anxiety, dizziness, headache, fever (especially during long term use of Luminal), respiratory depression, hypoventilation, apnea, movement disorders, bradycardia, hypotension, syncope, nausea, vomiting, constipation, megaloblastic anaemia, agranulocytosis, thrombocytopenia, osteomalacia (known as bone softening), bone disorders, bone fracture, liver damage, especially when phenobarbital is used for a long time,allergic skin reactions (very rarely *Stevens-Johnson* syndrome, toxic epidermal necrolysis), exanthema, angioedema (from the long term use of Luminal), the antiepileptic drug hypersensitivity syndrome, suicidal thoughts.

With parenteral use: Dupuytren’s contracture, hypocalcemia, aplastic anemia.

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

5. HOW TO STORE LUMINAL

Keep this medicine out of the sight and reach of children!

Do not use Luminal after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package.

6. OTHER INFORMATION

What Luminal 15 mg tablets contain:

The active substance is phenobarbital.

Each tablet contains 15 mg of phenobarbital.

The excipients are starch, lactose monohydrate, croscarmellose sodium, povidone, talc, and sodium starch glycolate.

What Luminal 60 mg tablets contain:

The active substance is phenobarbital.

Each tablet contains 60 mg of phenobarbital.

The excipients are starch, lactose monohydrate, povidone, talc, and sodium starch glycolate.

What Luminal 200 mg / 2 ml (10%) solution for injection contains:

The active substance is phenobarbital sodium.

Each ampoule of 2 ml contains 0.22 g of phenobarbital sodium equivalent to 0.2 g of phenobarbital (10%).

The excipients are ethyl alcohol, propylene glycol, benzyl alcohol, and water for injection.

Contents of the pack:

Luminal 15 mg, 60 mg tablets:

Box with 30 tablets.

Luminal 200 mg / 2 ml solution for injection:

Box with 10 ampoules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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