DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)

Date: 24th of May 2026

Subject: Phenobarbital, Luminal 0.1 g tablets - Packaging Leaflet Language Issue

Dear Healthcare Professional:

Nupco in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you about an issue related to the packaging language for one batch of Phenobarbital.

Summary:

- It has come to our attention that the following batch of Phenobarbital was distributed with packaging information, and a package insert written in Spanish only.
- The English-language patient information leaflet was not included as required.
- This issue is limited to the language of the labeling and does not affect the quality, safety, or efficacy of the product itself. However, the absence of English-language instructions may pose a risk of misinterpretation or misuse.
- Corrective and Preventive Actions have been taken to avoid any future similar events.
- The English version of the package leaflet is attached for your reference and use to provide it to patients who have received the affected batch to ensure correct usage.

Marketing Authorization Holder	Batch Number	Product Name
A.S.S.S. Kern Pharma	X002	Luminal 0.1 g

Note: The attached English patient leaflet should be used as the reference until the correct packaging is available. (Annex 1)

Further information:

Luminal belongs to the group of medicines called barbiturate antiepileptics.

This medicine is indicated to treat the following types of epilepsy:

- Generalized tonic-clonic crises and simple partial crises.

Reporting Adverse Events:

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

- To reports any side effect(s):
- **Saudi Arabia:**

- The National Pharmacovigilance Centre (NPC – Saudi Food and Drug authority (SFDA)):

- SFDA Call Center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa/
- QR Code:

Nupco Quality Liaison Officer

- Mobile: +966-59-463-4446
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Best Regards,
Abdulkarim A. Almutairi
Quality Liaison Officer

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

Annex 1: Phenobarbital Package Leaflet (English Version)

Introduction

Package leaflet: patient information

Luminal 100 mg tablets

phenobarbital

Read the entire package leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this prospect, as you may have to read it again.
- If you have any questions, consult your doctor or pharmacist.
- This medicine has been prescribed only to you, and you should not give it to other people, even if they have the same symptoms as you, as it can harm them.
- If you experience side effects, consult your doctor or pharmacist, even if it is a side effect that does not appear in this leaflet. See section 4.

Content of the prospectus

1. What Luminal tablets are and what it is used for

Luminal belongs to the group of medicines called barbiturate antiepileptics.

This medicine is indicated to treat the following types of epilepsy:

Generalized tonic-clonic crises and simple partial crises.

2. What you need to know before you take Luminal tablets

Do not take Luminal tablets:

- If you are allergic to phenobarbital, barbiturates, or any of the other ingredients of this medicine (listed in section 6).
- If you have acute alcohol poisoning.
- If you have respiratory illness in which the difficulty of breathing or obstruction is evident.
- If you take sleeping pills or painkillers simultaneously.
- If you have stimulant poisoning or sedative psychodrugs.
- If you have porphyria, kidney liver function disorders, or serious heart injuries.
- If you are taking atazanavir, saquinavir, daclatasvir, dasabuvir, dolutregravir, paritaprevir, ombitasvir, ledipasvir, simeprevir or sofosbuvir.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- If you require prolonged treatment (for 3 months), as you may develop a dependency syndrome,
- If you are taking vitamin D, because it can affect the metabolism of this vitamin,
- If you are an elderly person, since your biological functions are diminished and it may be necessary to reduce the dose (see section “3. How to take Luminal”),
- If your liver or kidneys are not working properly, your doctor should reduce the dose and carry out frequent checkups, as there is a risk of hepatic encephalopathy (see section “3. How to take Luminal”),
- If you are an alcoholic, your doctor should reduce the dose,
- If given to children, as the dose adjustment will be necessary (see section “3. How to Take Luminal”). If treatment is prolonged, consult your doctor. In this case, preventive treatment for rickets should be instituted,

- In some patients (old patients, children…), arousal, restlessness, mental confusion, as well as irritability and hyperactivity may appear in children,
- A small number of people treated with antiepileptic drugs such as Luminal have had thoughts of getting hurt or committed suicide. If you have these thoughts at any time, contact your doctor immediately,
- If symptoms of allergic reaction or liver problems appear, treatment should be discontinued, according to your doctor's instructions,
- Serious skin problems such as Stevens-Johnson syndrome (SSJ), toxic epidermal necrolysis (NET), reaction to the drug with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematic pustulosis (PEGA) associated with the use of this drug have been described:
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    - These skin rashes (Stevens-Johnson syndrome and toxic epidermal necrolysis) initially appear as reddish circular spots or spots, often with a central blister.
    - Symptoms of JSS/NET may include blistering, scaling, or bleeding in any part of your skin (including the lips, eyes, mouth, nose, genitals, hands, or feet) with or without rash.
    - Additional signs that may appear are sores in the mouth, throat, nose, genitals, and conjunctivitis (swollen, red eyes).
    - These skin rashes are often accompanied by flu-like symptoms, such as fever, chills, or muscle pain.
    - The period of increased risk of serious skin reactions is during the first weeks of treatment.
    - If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis using Luminal, you should not use the drug again at any time.
    - If you develop rashes with signs of swelling and/or color change or symptoms such as itching of the skin, stop taking Luminal, go to a doctor immediately, and tell them that you are taking this medicine.
    - Signs and symptoms of DRESS may include flu-like symptoms and a widespread rash with high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cells (eosinophilia) and enlarged lymph nodes.
    - Symptoms of PEGA appear at the start of treatment and may include a red, scaly, and generalized rash with bumps under the skin (including skin folds, chest, abdomen (including stomach), back, and arms) and blisters accompanied by fever.
    - If you develop severe skin reactions or any of the above-mentioned reactions, contact your doctor or healthcare professional immediately.

- Tell your doctor if you notice that at the beginning of your treatment, the frequency of seizures increases or new types of seizures appear,
- Treatment should not be discontinued abruptly as it can lead to seizures,
- Alcohol should not be taken with this medicine to not increase the sedative effect.

Woman of childbearing age/Contraception

If you are a woman with gestation and are not planning to become pregnant, you should use an effective method for birth control (contraception) throughout treatment with phenobarbital and up to two months after the end of treatment. Phenobarbital can affect the functioning of hormonal contraceptives, such as the birth control pill, and make them less effective in preventing pregnancy. Talk to your doctor, who will tell you the most appropriate type of contraceptive while you are taking phenobarbital

If you are a pregnant woman and are planning to become pregnant, talk to your doctor before leaving contraceptives and before you become pregnant about switching to other appropriate treatments to avoid exposure of the fetus to phenobarbital.

There is a risk of harm to the fetus if this medication is used during pregnancy. Women of childbearing potential should use effective contraception during treatment with this medicine (see “Pregnancy and Lactation”).

Other medicines and Luminal

Tell your doctor or pharmacist if you are taking, have recently taken, or may have to take any other medicines.

Certain medications may interact with Luminal, in these cases it may be necessary to change the dose or discontinue treatment.

- Alcoholic beverages or medicines containing alcohol,
- Antidepressants (treatment of depression),
- Metadone,

- Other central nervous system depressant medications: morphine derivatives (analgesics, antitussives and replacement therapies), benzodiazepines and other medications to treat anxiety, sedative, hypnotic, neuroleptic, sedative H1 antihistamines, central antihypertensives, baclofen, and thalidomide,
- Methotrexate (treatment of arthritis),
- Oral contraceptives (see section Woman of childbearing age/Contraception).

- ***You should not take*** *Luminal along with:*

- Atazanavir, saquinavir (protease inhibitor used to treat HIV infection), daclatasvir, dasabuvir, dolutregravir, paritaprevir, ombitasvir, ledipasvir, simeprevir, sofosbuvir (drugs used to treat hepatitis C in adults).

- ***Caution*** *should be with associations with the following medications:*:

- Ifosfamide (used in chemotherapy), if Luminal is used as a treatment for epilepsy,
- Oral anticoagulants (used to prevent or delay blood clotting)
- Antiproteases: antivirals such as amprenavir, indinavir and nelfinavir,
- Cyclosporin, tacrolimus (reduce the immune response),
- Corticoids,
- Digitoxin (drugs that act on the cardiovascular system),
- Dihydropyridines (high blood pressure treatment),
- Disopyramide (drug for the treatment of tachycardia),
- Doxycycline (treatment of bacteria infections),
- Thyroid hormones (treatment of hypothyroidism),
- Hydroquinidine, quinidine (treatment of heart arrhythmias),
- Itraconazole (treatment of fungal infections),
- Montelukast (preventive treatment for asthma),
- Theophylline and its derivatives such as aminophylline (used as diuretics, vasodilators or anti-asthmatics),
- Zidovudine (treatment of virus infections)

- Estrogens and progestogens (not used as contraceptives).

- ***tener en consideración****Associations with the following medicines should be* considered:

- Estroprogestogens and progestogens used as contraceptives, since it may decrease the effectiveness of contraceptive, so the use of alternative contraceptive methods should be considered (see section "Women of childbearing age/contraception"),
- Ritonavir, simeprevir, dolutegravir, as antiretrovirals of the protease inhibitor group, since they can decrease the antiprotease efficacy,
- Anticancer drugs, as it can lead to a lower risk of exposure of these drugs for the treatment of cancer,
- Lamotrigine (antiepileptic),
- Beta-blocking medications: alprenolol, metoprolol and propranolol (used for the treatment of vascular disorders, anxiety, extrapyramid disorders or tremors),
- Carbamazepine (antiepileptic),
- Procarbazine (used in chemotherapy),
- Amitriptyline/amitriptylinoxide (antidepressants),
- Apixaban, ticagrelor (antithrombotic), since it can decrease the effectiveness.

- ***Effect of other medicines on Luminal:***

- Derivatives of folic acid (treatment of certain vitamin deficiencies), decrease the efficacy of phenobarbital.

- ***Other drug interactions with Luminal:***

- Valproic acid (treatment of epilepsy and bipolar disorder)
- Phenytoin (antiepileptic).

Use of Luminal tablets with food, beverages and alcohol.

During treatment with this medicine should not consume alcoholic beverages.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, consult your doctor or pharmacist before using this medicine.

Neurodevelopmental disorders (developmental delays due to brain developmental disorders) have been reported among children exposed to phenobarbital during pregnancy. Risk studies remain conflicting.

Pregnancy

Phenobarbital crosses the placenta.

If taken during pregnancy, phenobarbital can lead to serious birth defects and affect the child's development as he or she grows. Birth defects that have been reported in the studies include the cleft lip (cleft in the upper lip) and the cleft palate (cleft in the roof of the mouth) and heart abnormalities. Other congenital abnormalities have also been reported, such as malformation of the penis (hypospadias), a lower than normal head size, and facial, finger and finger abnormalities. Babies born to mothers who use phenobarbital during pregnancy may also be at a higher risk of being smaller than expected.

Neurodevelopmental disorders (developmental delays due to brain development disorders) have been reported among children exposed to phenobarbital during pregnancy. Risk studies remain conflicting.

If you take phenobarbital during pregnancy, you have a higher risk than other women of having a child with birth defects that require medical treatment. In the general population, the basic risk of major malformations is 2-3%. This risk increases about 3-fold in women taking Luminal.

You should not use phenobarbital if you are pregnant, unless no other treatment works.

Talk to your doctor right away if you are pregnant. Your doctor should explain the possible effects of phenobarbital treatment on your baby and the risks and benefits should be carefully evaluated. Do not stop taking phenobarbital until you have consulted your doctor, as abrupt discontinuation of the drug may increase the risk of developing seizures, which can have detrimental effects for you and the fetus.

If you have taken Luminal during the last trimester of pregnancy, proper follow-up should be done to detect possible disorders in the newborn, such as seizures, excessive crying, muscle weakness, suction disorders.

Luminal can cause, in some cases, in newborns, bleeding in the first 24 hours of the baby's life, if the mother is in treatment with this medicine.

It is recommended as a preventive treatment, to administer vitamin K1 to the mother orally before and at the time of birth, and adequate supplements to the newborn.

A condition of dependence, withdrawal syndrome (with seizures, hyperreactivity) and rarely, a moderate withdrawal syndrome (with abnormal movements, sucking problems and bone mineralization problems) may also appear.

Breastfeeding

If you are breastfeeding, the administration of phenobarbital is not advised, as it goes into breast milk, which can have repercussions on the newborn.

Driving and use of machines

This medicine may produce symptoms such as drowsiness, dizziness, or vision disturbances, and decrease reaction capacity. These effects, as well as the disease itself can hinder your ability to drive vehicles or operate machines. Therefore, do not drive, or operate machines, or practice other activities that require special attention, until your doctor assesses your response to this drug.

Luminal contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. essentially "sodium-free".

3. How to take Luminal tablets

Follow exactly the instructions for this medicine contained in this package leaflet or those indicated by your doctor or pharmacist. If in doubt, consult your doctor or pharmacist again.

Do not stop treatment abruptly, as it could lead to seizures (see section "Warnings and precautions"), it is advisable to do so gradually.

Tablets should be taken without chewing with a sufficient amount of warm liquid.

Adults

The recommended start dose is 50 - 100 mg daily. This dose should be given divided into 2 daily doses.

The dose will be progressively adapted to the appropriate individual maintenance dose.

The recommended maintenance dose is 50-250 mg per day.

Use in children

The recommended starting and maintenance doses are 3 to 5 mg per kg of body weight per day, and can be administered in two doses.

If treatment is prolonged, your doctor may recommend preventive treatment against rickets.

Patients with impaired function in the liver or kidneys

If your liver or kidneys are not working properly, your doctor should assess the benefits and risks of administering this medicine and should adjust the dose according to your situation.

elderly patients

Your doctor will adjust your dose and clinical and plasma level monitoring will be necessary.

If you take more Luminal than you should

In case of overdose or accidental ingestion, immediately consult your doctor, pharmacist or call the Toxicological Information Service. Phone: 91 562 04 20.

In the hour following the massive ingestion of the drug, nausea, vomiting, headache, obsession, mental confusion, and possibly, even coma accompanied by a characteristic neurovegetative state (with a decrease in respiratory rate (irregular bradypnea), obstruction of the trachea and bronchi and decrease in blood pressure) appear.

The treatment indicated in this case is forced diuresis, alkalization, respiratory assistance, antibiotic treatment, potassium intake and even hemodialysis or peritoneal dialysis if necessary.

If you forget to take Luminal tablets

Do not take a double dose to make up for the missed doses.

4. Possible adverse effects

Like all medicines, this medicine can cause side effects, although not everyone gets it.

These adverse effects can be defined according to their frequency of occurrence as:

Very common (may affect more than 1 in 10 people)

Common (may affect up to 1 in 10 people)

Uncommon (may affect up to 1 in 100 people)

Rare (may affect up to 1 in 1,000 people)

Very rare (can affect up to 1 in 10,000 people)

Not known frequency (cannot be estimated from available data).

Common side effects (may affect up to 1 in 10 patients):

- **Alteration in the hand tendons (Dupuytren contractures),**
- **Allergic dermatitis, particularly rashes associated with stains or red, that end with scaling (scarlatiniform or morbiliform maculopapular rashes),**
- **Increased gamma-glutamyltransferase, transaminases and alkaline phosphatase in blood,**
- **Nausea, vomiting,**
- **Drowsiness (difficulties in waking up, sometimes added to speech problems),**
- **Disorders in thought and memory,**
- **Deterioration of memory,**
- **Behavioral disorders (such as agitation or aggression).**

Uncommon side effects (may affect up to 1 in 100 patients):

- **Changes in mood,**
- **Sleep/insomnia disorders,**
- **Problems of coordination and balance,**
- **Pain in the joints (arthralgia).**

Rare side effects (may affect up to 1 in 1,000 patients):

- **Alteration of attention.**

Unknown frequency (cannot be estimated from available data)

- A condition in which the number of red blood cells, white blood cells and platelets in the blood is lower than normal (**pancytopenia),**
- **aplastic anemia,**
- **Agranulocytosis,**
- **Anemia (reduction in the number and increase in the size of red blood cells) due to folic acid deficiency,**
- **Reduction in neutrophil count in blood (neutropenia),**
- **Leukopenia and thrombocytopenia (alterations in blood cells),**
- **Loss of memories (amnesia),**
- **Abnormal movement of muscles such as tics, tremors (dyskinesia),**
- **Hepatitis,**
- **Bone alterations, including osteopenia and osteoporosis (bone decalcification) and fractures in patients with prolonged treatment with phenobarbital. Talk to your doctor or pharmacist if you are on prolonged treatment with antiepileptics, have a history of osteoporosis or take steroids,**
- **Treatment should be removed if serious adverse reactions affecting liver and/or skin function are observed or hypersensitivity reactions occur,**
- **Decreased serum thyroid hormones,**
- **Fixed eruption,**
- **Exfoliative dermatitis,**

- **Dependence.**

If treatment is prolonged, it may develop mental or physical dependence. Therefore, if you stop treatment abruptly, you may suffer from headache, muscle pain, anxiety, tension, restlessness, confusion, and irritability. In severe cases, other symptoms may appear such as depersonalization, increased hearing sensitivity, tingling and limb cramps, light intolerance, sounds and physical contact, hallucinations or seizures.

Possible severe skin reactions, including extremely rare cases such as Stevens-Johnson syndrome, toxic epidermal necrolysis, and exfoliative dermatitis. Symptoms of JSS/NET may include blistering, scaling, or bleeding in any part of your skin (including the lips, eyes, mouth, nose, genitals, hands, or feet) with or without rash. You may also have flu-like symptoms like fever, chills, or muscle pain.

Reaction to the drug with eosinophilia (increase in white blood cells) and systemic symptoms (DRESS): Signs and symptoms of DRESS may include flu-like symptoms and a generalized rash with high body temperature and enlarged lymph nodes. Abnormal blood test results may include increased levels of liver enzymes and an increase in a type of white blood cells (eosinophilia) and enlarged lymph nodes.

At the start of treatment, PEGA symptoms may include a red, scaly, and generalized rash with bumps under the skin (including folds of the skin, chest, abdomen (including the stomach), back, and arms) and blisters accompanied by fever.

Care should be taken when replacing phenobarbital with another antiepileptic, such as phenytoin or carbamazepine, as they can rarely result in a cross-reaction between phenobarbital and either medication.

Treatment should be removed if serious adverse reactions affecting liver and/or skin function are observed or hypersensitivity reactions occur.

Communication of adverse effects

If you experience any type of side effects, consult your doctor or pharmacist, even if these are possible side effects that do not appear in this leaflet. You can also communicate them directly through the Spanish Drug Surveillance System for Human Use:

www.notifiifirmam.es. By communicating adverse effects you can help provide more information about the safety of this medicine.

5. Conservation of Luminal tablets

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiration date is the last day of the month indicated.

This medicine does not require special storage conditions.

Medicines should not be thrown down the drains or garbage. Deposit the packaging and medications you do not need at the pharmacy's SIGRE Point. If in doubt, ask your pharmacist how to get rid of the packaging and medications you don't need. This will help protect the environment.

6. Contents of the pack and additional information

Composition of Luminal tablets

The active substance is phenobarbital.

The other excipients are: corn starch, talc, sodium potato carboxymethyl starch (Type A) and magnesium stearate.

Appearance of the product and contents of the package

PVC/Aluminium Blister with 50 tablets.

Marketing Authorisation Holder and Manufacturer

Kern Pharma, S.L.

Venus, 72 - Pol. Ind. Columbus II

08228 Terrassa - Barcelona

Spain

Date of last revision of this prospectus : March 2025

Detailed information on this medicine is available on the website of the Spanish Agency for Medicines and Health Products (AEMPS) http:// www.aemps.gob.es /