

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The dispensing of this medicine
requires a doctor's prescription

Read this package insert carefully in its entirety
before using this medicine

The format of this leaflet was determined by the
Ministry of Health and its content was checked and approved

Epanutin 100 mg

Capsules

Composition: Each capsule contains 100 mg Phenytoin Sodium.

Each capsule contains lactose monohydrate 96.15 mg.

Inactive ingredients: Lactose monohydrate, magnesium stearate, gelatin, erythrosine E127, quinoline yellow E104, titanium dioxide E171, black printing composition: shellac, propylene glycol, black iron oxide E172, N-butyl alcohol, isopropyl alcohol and industrial methylated spirit, ammonium solution, potassium hydroxide.

Therapeutic group: Anticonvulsant.

Therapeutic activity: For the treatment of epilepsy.

When should the preparation not be used?

Do not use this medicine if you are sensitive to any of its ingredients or to hydantoin.

Do not use this medicine without consulting a physician before starting treatment:

If you are pregnant, because this medicine may harm the fetus. If you were exposed to this medicine during pregnancy, especially in the first trimester, you should consult with one of the teratologic centers for assessment of the risk of harm to the fetus.

If you are breastfeeding. Use of this medicine is not recommended for nursing mothers.

Do not use this medicine without consulting a physician before starting treatment if you are suffering from porphyria, if you are suffering or have suffered in the past, from impaired function of the heart and vascular system, the liver, the kidney/urinary tract, the blood system (coagulation), the immune system, from diabetes, if you have experienced in the past hypersensitivity reactions to anticonvulsants (Anticonvulsant Hypersensitivity Syndrome [AHS]).

How will this medicine affect your daily life?

Use of this medicine may impair alertness and therefore caution should be exercised when driving a car, operating dangerous machinery and in any activity which requires alertness.

Children should be cautioned against bicycle riding or playing near roads and the like.

Do not drink wine or alcoholic beverages while under treatment with this medicine. During treatment with this medicine it is important to maintain good oral hygiene in order to prevent gum problems.

Warnings: During treatment with this medicine, the following tests should be performed: blood, hepatic function, electroencephalogram (EEG), and phenytoin blood concentrations.

In prolonged treatment with the medicine, tests for bone density and vitamin D levels should be performed periodically.

Treatment with this medicine can increase the risk of suicidal thoughts and behavior.

If you are sensitive to any type of food or medicine, inform your physician before commencing treatment with this medicine.

Before any kind of surgery (including dental surgery) or medical treatment inform your physician that you are taking this medicine.

Attention: This medicine may affect blood levels and laboratory test results of PBI (protein-bound iodine), dexamethasone, metyrapone, alkaline phosphatase, glucose, GGT, calcium and sugar.

The preparation contains lactose and may cause an allergic reaction in patients sensitive to lactose.

Drug Interactions: If you are taking another drug, including non-prescription medicines and nutritional supplements, or if you have just finished treatment with another medicine, inform the attending physician, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups:

Drugs affecting the central nervous system [e.g. sedatives (such as: chloridiazepoxide, diazepam, disulfiram, methylphenidate, trazodone, viloxazine), anesthetics (such as: halothane), antidepressants (such as: tricyclics, fluoxetine, fluvoxamine, sertraline, clozapine, paroxetine), antihistamines].

Antibacterial drugs: chloramphenicol, sulfonamides, rifampin, erythromycin, isoniazid, ciprofloxacin, doxycycline, praziquantel, tetracycline.

Antifungal drugs: fluconazole, ketoconazole, miconazole, amphotericin B, itraconazole, azoles.

Medicines for the treatment of cancerous growths: fluorouracil.
Medicines for the treatment of gastric ulcers: cimetidine, sucralfate, omeprazole.
Xanthines: aminophylline, theophylline.
Anticoagulants from the coumarin group.
Other antiepileptic and anticonvulsant drugs (felbamate, succinimide, vigabatrin, carbamazepine, barbiturates, valproic acid, sodium valproate, lamotrigine).
Hormones: estrogens, corticosteroids.
Hypoglycemic drugs: tolbutamide, diazoxide, chlorpropamide, glyburide.
Analgesic and anti-inflammatory drugs: azapropazone, phenylbutazone, salicylates.
Cardiovascular agents and drugs treating hypertension: amiodarone, dicumarol, diltiazem, nifedipine, ticlopidine, reserpine, digitoxin, nicardipine, nimodipine, quinidine, verapamil.
Diuretics: furosemide.
Neuromuscular blocking agents: alcuronium, pancuronium, vecuronium.
Other drugs: cyclosporine, methadone, nelfinavir, teniposide, vitamin D, folic acid and nutritional supplements.
Do not take or stop taking another kind of medicine without consulting your physician.

Use of this drug may decrease the effectiveness of oral contraceptives, therefore you should use a different or additional means of birth control.

Side Effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: constipation, dizziness, mild drowsiness.

Side effects that require special attention:

Suicidal thoughts and behavior, confusion, mild nervousness, insomnia, headache, speech or coordination disorders, involuntary eye movements, taste disturbances, tingling sensation, hypotension, nausea, vomiting, fever, tremor, muscle weakness or pain, joint pains, increased risk of fractures, osteoporosis, hypocalcemia, hypophosphatemia, changes in blood count (such as: thrombocytopenia and leukopenia), anemia, hyperglycemia, jaundice, liver impairment, systemic lupus erythematosus, excessive hairiness, hyperproliferation of the gum tissue, swelling of the lips, Peyronie's disease, skin rash with irritation, Stevens-Johnson syndrome - continue treatment and refer to your physician immediately.

Hypersensitive reaction to the medicine, including rash, fever and enlargement of the lymph nodes - stop treatment and refer to the physician immediately.

Anaphylactic shock, respiratory distress up to loss of consciousness (have been reported in parenteral use or in overdose) - stop treatment and refer to your physician immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your physician immediately.

Adverse reactions and drug interactions in children and infants:

Parents must inform the attending physician about any side effect, as well as any additional medicine being taken by the child!

Dosage: Dosage is according to physician's instructions only.

Do not exceed the recommended dosage.

In children: If the daily dosage cannot be divided equally, the larger dose should be given at bedtime.

Attention: Allow a lapse of at least two hours between taking this medicine and taking antacids that include calcium, other preparations that include calcium and molindone hydrochloride.

Directions for Use: Swallow the capsule with a glass of water.

Take the medicine with a meal.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the physician.

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your physician.

Reduction in dosage will usually be done gradually.

Your physician may want you to carry a medical identification card stating that you are taking this medicine.

Avoid Poisoning! This medicine, and all other medicines, must be stored in a properly closed place out of the reach of children and/or infants, to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by a physician! This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. Do not give this medicine to your relatives, neighbors or acquaintances. Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage: Store at room temperature, below 25°C.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

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