Package leaflet: Information for the patient

Epanutin® 100 mg Hard Capsules
(phenytoin sodium)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Epanutin Hard Capsules are and what they are used for
2. What you need to know before you take Epanutin
3. How to take Epanutin
4. Possible side effects
5. How to store Epanutin
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1. What Epanutin Hard Capsules are and what they are used for

This medicine contains phenytoin, which is one of a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy.

Epanutin can be used to control a variety of epileptic conditions, to control or prevent seizures during or after brain surgery or severe head injury. Epanutin can also be used to treat trigeminal neuralgia (facial nerve pain).

You should ask your doctor if you are unsure why you have been given Epanutin Capsules, if you do not feel better or if you feel worse.

2. What you need to know before you take Epanutin

Do not take Epanutin
- if you are allergic (hypersensitive) to phenytoin, or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other medicines for epilepsy
- if you are taking medicines for HIV infection, such as delavirdine.

Warnings and precautions
Talk to your doctor or pharmacist before you take Epanutin if you suffer from or have suffered in the past from any of the following conditions:
- Liver disease
- Kidney disease
- Porphyria (an inherited disease that affects haemoglobin biosynthesis)
- Alcohol dependence.
- If you are of Chinese or Thai origin and tests have shown that you carry the genetic variant HLA-B*1502.

- If you are of Taiwanese, Japanese, Malaysian or Thai origin and tests have shown that you carry the genetic variant CYP2C9*3.

Epanutin can cause problems with your heart, including a slow heartbeat. Let your healthcare provider know right away if you have these symptoms.

You should be administered Epanutin with caution if you suffer from kidney or liver problems.

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

Potentially life-threatening skin rashes (for example Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Epanutin, 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 potentially life-threatening 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 Epanutin, you must not be re-started on Epanutin at any time.

If you develop a rash or these skin symptoms, seek urgent advice from a doctor and tell him that you are taking this medicine. Consult your doctor before discontinuing Epanutin.

Phenytoin is not effective for the seizure type, absence (petit mal) seizures.

Phenytoin may affect the breakdown of the sugar, glucose, and may prevent the release of the hormone, insulin which could lead to high blood sugar. This is particularly important if you are diabetic.

Black patients may be at greater risk of liver problems, serious skin reactions and allergic reactions.

Cases of swelling of the face, mouth (lip, gum, tongue) and neck that can lead to life-threatening breathing difficulty have been reported in people being treated with phenytoin. If at any time you have these signs or symptoms immediately contact your doctor.

There is a risk of harm to the unborn child if Epanutin is used during pregnancy. Women of childbearing age should use effective contraception during treatment with Epanutin (see Pregnancy, contraception in women, and breast-feeding).

Other medicines and Epanutin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines can affect the way Epanutin works, or Epanutin itself can reduce the effectiveness of other medicines taken at the same time. These include (Not all medicines are listed here. Talk with your doctor or pharmacist):

- Medicines used for heart and circulation problems (e.g. dicoumarol, digitoxin, digoxin, disopyramide, mexiletine, nisoldipine, amiodarone, furosemide, quinidine, reserpine and calcium channel blockers including diltiazem and nifedipine)

- Medicines used to prevent blood clots, anticoagulants (e.g. apixaban, dabigatran, edoxaban, rivaroxaban, warfarin), antiplatelets (e.g. ticagrelor)
- Medicines used for epilepsy (e.g. carbamazepine, lacosamide, lamotrigine, phenobarbital, sodium valproate and valproic acid, topiramate, oxcarbazepine, succinimides including ethosuximide and vigabatrin)
- Medicines used to treat fungal infections (e.g. amphotericin B, fluconazole, itraconazole, ketoconazole, posaconazole, voriconazole and miconazole)
- Medicines used for tuberculosis and other infections (e.g. chloramphenicol, isoniazid, rifampicin, sulfonamides, sulfadiazine, sulfamethiazole, sulfamethoxazole-trimethoprim, sulfaphenazole, sulfisoxazole, doxycycline and ciprofloxacin)
- Medicines used for stomach ulcers (e.g. omeprazole, sucralfate, the medicines known as H_2 antagonists including cimetidine, ranitidine, famotidine and some antacids)
- Medicines used for asthma and bronchitis (e.g. theophylline)
- Medicines used for pain and inflammation (e.g. phenylbutazone, salicylates including aspirin and steroids)
- Medicines used for sleeplessness, depression and psychiatric disorders (e.g. chlordiazepoxide, clozapine, diazepam, disulfiram, fluoxetine, methylphenidate, paroxetine, phenothiazines, quetiapine, trazodone, tricyclic antidepressants, fluvoxamine, sertraline, viloxazine)
- Medicines used for diabetes (e.g. tolbutamide)
- Some hormone replacement therapies (oestrogens), oral contraceptives (the birth control pill) (see Pregnancy, contraception in women, and breast-feeding)
- Medicines used for organ and tissue transplants, to prevent rejection (e.g. ciclosporin, tacrolimus)
- Medicines used for cancer (antineoplastic agents, e.g. teniposide and fluorouracil, capecitabine, bleomycin, carboplatin, cisplatin, doxorubicin, methotrexate)
- Medicines used to lower high blood cholesterol and triglycerides (e.g. atorvastatin, fluvastatin, simvastatin)
- Medicines used in the treatment of HIV infection (e.g. delavirdine, efavirenz, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir)
- Medicines used to expel parasitic worms from the body (e.g. albendazole, praziquantel)
- Muscle relaxants used for surgery (neuromuscular blockers), some anaesthetic drugs (e.g. halothane, methadone)
- Some products available without a prescription (e.g. folic acid, vitamin D).

Your doctor may need to test the amount of phenytoin in your blood to help decide if any of these medicines are affecting your treatment.

The herbal preparation St John's wort (*Hypericum perforatum*) should **not** be taken at the same time as this medicine. If you already take St John's wort, consult your doctor before stopping the St John's wort preparation.
Epanutin capsules may also interfere with certain laboratory tests that you may be given.

Epanutin with food, drink and alcohol
Epanutin can be taken before or after food and drink. Drinking a lot of alcohol can also affect the concentration of phenytoin in your blood.

Pregnancy, contraception in women, and breast-feeding

Pregnancy

Epanutin can cause major birth defects. If you take Epanutin during pregnancy your baby has up to 3 times the risk of having a birth defect than women not taking an antiepileptic medication. Major birth defects including growth, skull, facial, nail, finger and heart abnormalities have been

reported. Some of these may occur together as part of a fetal hydantoin syndrome. Your unborn baby should be closely monitored if you have taken Epanutin while pregnant. Epanutin should not be used during pregnancy unless nothing else works for you.

Problems with neurodevelopment (development of the brain) have been reported in babies born to mothers who used phenytoin during pregnancy. Some studies have shown that phenytoin negatively affects neurodevelopment of children exposed to phenytoin in the womb, while other studies have not found such an effect. The possibility of an effect on neurodevelopment cannot be ruled out.

There have been isolated reports of tumours, including tumours affecting nerve tissue, in children whose mothers received phenytoin during pregnancy.

If you take Epanutin during pregnancy, your baby is at risk for bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this. Moreover, your child should be closely monitored.

Contraception in Women

If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with Epanutin. Epanutin may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Epanutin.

If you are a woman of childbearing age and are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to phenytoin.

If you are or think you might be pregnant, tell your doctor straight away. You should not stop taking your medicine until you have discussed this with your doctor. Stopping your medication without consulting your doctor could cause seizures which could be dangerous to you and your unborn child. Your doctor may decide to change your treatment. Closer monitoring of your unborn child is also recommended.

Breast-feeding
Epanutin passes into breast milk. You should not breast-feed if you are taking Epanutin.

Driving and using machines
Epanutin may cause dizziness or drowsiness. If you experience these symptoms, do not drive or use any tools or machinery and contact your doctor.

Epanutin contains lactose monohydrate
Lactose monohydrate is a type of sugar. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Epanutin contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium free’.

3. How to take Epanutin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It is best to take Epanutin at the same time each day.
Swallow the capsules whole, with plenty of water.

Adults
The amount of Epanutin needed varies from one person to another. Most adults need between 200 mg and 500 mg a day either as a single or divided dose. Occasionally higher doses are needed.

Children and adolescents
Infants and children usually start on a dose that depends on their weight (5 mg per day for every kg they weigh) and is given as a divided dose, twice a day. The dose is then adjusted up to a maximum of 300 mg a day.

Elderly
Due to decreased clearance of Epanutin, lower or less frequent dosing may be needed. The dose of Epanutin for elderly patients who may be taking other medicines may also need careful consideration and adjustment by their doctor.

Kidney or liver problems
Make sure your doctor knows if you have liver or kidney problems as you may need your dose adjusted.

If you take more Epanutin than you should
Epanutin is dangerous in overdose. If you accidentally take too much Epanutin contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any Epanutin left or not.

If you forget to take Epanutin
If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. **Do not take a double dose to make up for a missed dose.**

If you stop taking Epanutin
Do not stop taking Epanutin unless your doctor tells you to. If you suddenly stop taking this medicine you may have a seizure. Should you need to stop taking Epanutin, your doctor will have decided which the best method is for you.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body). There is a higher incidence of this in black patients.
- If you develop potentially life-threatening skin rashes that cause blistering, (this can also affect the mouth and tongue). These may be signs of a condition known as Stevens-Johnson syndrome, or toxic epidermal necrolysis (TEN). These have been reported very rarely.

- If you notice bruising, fever, you are looking pale or you have a severe sore throat. These may be the first signs of an abnormality of the blood, including decreases in the number of red cells, white cells or platelets. Your doctor may take regular blood samples to test for these effects.
- Skin rash and fever with swollen glands, particularly in the first two months of treatment, as these may be signs of a hypersensitivity reaction known as Anticonvulsant Hypersensitivity Syndrome (AHS). If these are severe and you also experience pain and inflammation of the joints this could be related to a condition called systemic lupus erythematosus.
- Skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia), and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine), as they may be signs of a hypersensitivity reaction (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS)).
- Areas of red skin with small elevated sterile pustules (small blisters filled with white/yellow fluid). There tends to be more disease in skin folds. Swelling of the face can occur as well (Acute Generalized Exanthematous Pustulosis (AGEP)).
- If you experience confusion or have a severe mental illness, as this may be a sign that you have high amounts of phenytoin in your blood. On rare occasions, when the amount of phenytoin in the blood remains high, irreversible brain injury has occurred. Your doctor may test your blood to see how much phenytoin is in the blood and may change your dose.

Other side effects that may occur are:

- **Effects on your nervous system:** Unusual eye movements, unsteadiness, difficulty in controlling movements, shaking, abnormal or uncoordinated movements, slurred speech, confusion, pins and needles or numbness, drowsiness, dizziness, vertigo, sleeplessness, nervousness, twitching muscles, headaches and change in taste.
- **Effects on your skin:** life-threatening skin rashes that cause blistering (this can affect the mouth and tongue), skin rash including measles-like reactions which are mild, hives.
- **Effects on your stomach and intestines:** feeling sick, being sick and constipation.
- **Effects on your blood and lymph system:** swelling of the lymph glands, a decrease in the number of a type of red blood cell (pure red cell aplasia).
- **Effects on your liver and kidney:** inflammation of the kidneys and liver, liver damage or liver failure which can lead to death (seen as yellowing of the skin and whites of the eye).
- **Effects on your reproductive system and breasts:** changes in the shape of the penis, painful erection.
- **Effects on your hands, face and body:** changes in the hands with difficulty in straightening the fingers, changes in facial features, enlarged lips or gums, increased or abnormal body or facial hair.
- **Effects on medical tests:** increased levels of blood sugar, or decreased levels of blood calcium, folic acid and vitamin D. If you also do not get enough vitamin D in your diet or from exposure to sunlight, you may suffer from bone pain or fractures. Taking phenytoin may cause abnormal thyroid test results.
- **Effects on your respiratory system:** problems breathing, inflammation of the lining of the lung.
- **Effects on your immune system:** problems with the body's defence against infection, inflammation of the wall of the arteries and immunoglobin abnormalities.
- **Effects on your bones**: there have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine

Ireland
HPRA Pharmacovigilance. Website: www.hpra.ie.

Malta
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Epanutin

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

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is printed on the bottle label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Epanutin contains
Epanutin 100 mg Capsules contain 100 mg of the active ingredient, phenytoin sodium. The other ingredients are lactose monohydrate, magnesium stearate and sodium laurilsulfate (see section 2 "Epanutin contains sodium").

The gelatin capsule shells contain the colouring titanium dioxide (E171), erythrosine (E127) and quinoline yellow (E104). The printing ink contains the following: shellac, black iron oxide (E172) and propylene glycol. It may also contain potassium hydroxide.

What Epanutin looks like and contents of the pack
Epanutin 100 mg capsules are half white and half orange hard capsules marked with "EPANUTIN 100" and available in packs containing 84 capsules. The capsules are packed in a plastic container which contains a desiccant.

Marketing Authorisation Holder

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