

PACKAGE LEAFLET: INFORMATION FOR THE USER

Epanutin™ 25mg Hard Capsules

(phenytoin sodium)

Read all of this leaflet carefully before you start taking 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

The name of your medicine is Epanutin 25mg Hard Capsules, but will be referred to as Epanutin throughout this leaflet.

In this leaflet:

1. What Epanutin is and what it is used for
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4. Possible side effects
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1. What Epanutin is and what it is used for

Epanutin 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.

2. Before you take Epanutin

Do not take Epanutin

- if you are allergic (hypersensitive) to Phenytoin, or any of the other ingredients of Epanutin.

Take special care with Epanutin

Medicines are not always suitable for everyone. Your doctor needs to know before you take Epanutin if you suffer from or have suffered in the past from any of the following conditions:

- Liver disease.
- Porphyria (an inherited disease that affects haemoglobin biosynthesis).

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 (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, stop taking Epanutin, seek urgent advice from a doctor and tell him that you are taking this medicine.

This risk of these serious skin side effects may be associated with a variant in genes in a subject with Chinese or Thai origin. If you are of such origin and have been tested previously carrying this genetic variant (HLA-B*1502), discuss this with your doctor before taking 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.

Taking other medicines

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:

- Medicines used for heart and circulation problems (dicoumarol, digitoxin, amiodarone, furosemide, quinidine, reserpine, warfarin, and calcium channel blockers e.g. diltiazem and nifedipine).
- Medicines used for epilepsy (carbamazepine, lamotrigine, phenobarbital, sodium valproate and valproic acid, succinimides e.g. ethosuximide and vigabatrin).
- Medicines used to treat fungal infections (e.g. amphotericin B, fluconazole, itraconazole, ketoconazole and miconazole).
- Medicines used for tuberculosis and other infections (chloramphenicol, isoniazid, rifampicin, sulphonamides, doxycycline, ciprofloxacin and nelfinavir).
- Medicines used for stomach ulcers (omeprazole, sucralfate, the medicines known as H₂ antagonists e.g. cimetidine, ranitidine, famotidine and some antacids).
- Medicines used for asthma and bronchitis (theophylline).
- Medicines used for pain and inflammation (phenylbutazone, salicylates e.g. aspirin and steroids).
- Medicines used for sleeplessness, depression and psychiatric disorders (chlordiazepoxide, clozapine, diazepam, disulfiram, fluoxetine, methylphenidate, paroxetine, phenothiazines, trazodone, tricyclic antidepressants, fluvoxamine, sertraline and viloxazine).
- Medicines used for diabetes (tolbutamide).
- Some hormone replacement therapies (oestrogens), oral contraceptives (the birth control pill).
- Medicines used for organ and tissue transplants, to prevent rejection (cyclosporin).
- Medicines used for cancer (antineoplastic agents, e.g. teniposide and fluorouracil).
- Muscle relaxants used for surgery (neuromuscular blockers), some anaesthetic drugs (halothane) and methadone.
- Some products available without a prescription (folic acid, theophylline, 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 may also interfere with certain laboratory tests that you may be given.

Taking Epanutin with food and drink

Epanutin can be taken before or after food and drinks. Drinking a lot of alcohol can also affect the concentration of Phenytoin in your blood.

Pregnancy and Breast-feeding

If you think you might be pregnant, or are planning to get pregnant, tell your doctor before you take Epanutin.

You should not take Epanutin if you are breast-feeding.

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

Driving and using machines

Epanutin may cause dizziness or drowsiness, especially during the first few weeks of treatment. If you experience these symptoms, do not drive or use any tools or machinery.

Important information about some of the ingredients of Epanutin

Epanutin contains lactose, 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.

3. How to take Epanutin

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 200mg and 500mg a day either as a single or divided dose. Occasionally higher doses are needed.

Children

Infants and children usually start on a dose that depends on their weight (5mg 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 300mg a day.

Elderly

The dose of Epanutin for elderly patients who may be taking other medicines may also need careful consideration and adjustment by their doctor.

Always take Epanutin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are still not sure.

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 how to take this Epanutin, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Epanutin 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).
- 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. Your doctor will stop your treatment in these cases.
- 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.
- If you experience a state of 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 taste change.
- **Effects on your skin:** skin rash including measles-like reactions which are mild.
- **Effects on your stomach and intestines:** feeling sick, being sick and constipation.
- **Effects on your blood and lymph system:** swelling of the lymph glands.
- **Effects on your liver and kidney:** inflammation of the kidneys and liver, liver damage (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.
- **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.
- **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.

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 Epanutin

Keep out of the reach and sight of children.

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

Do not use Epanutin after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Epanutin contains

Epanutin 25mg Capsules contain 25mg of the active ingredient, phenytoin sodium. The other ingredients are lactose monohydrate, magnesium stearate and sodium laurilsulfate. The gelatin capsule shells contain the colouring titanium dioxide (E171), patent blue V (E131) and erythrosine (E127). 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 25 mg capsules are half white and half purple hard capsules marked with "Epanutin 25" and available in packs containing 28 capsules.

Manufactured by: Goedecke GmbH, Mooswaldallee 1, D-79090, Freiburg, Germany

Procured from within the EU and repackaged by PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK

Epanutin 25mg Hard Capsules, PPA 1328/147/1

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