

Package leaflet: Information for the user

# Epanutin® 100mg 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.

The name of your medicine is Epanutin 100mg capsules but will be referred to as Epanutin throughout this leaflet.

What is in this leaflet:

1. What Epanutin is and what it is 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
6. Contents of the pack and other information

## 1. What Epanutin is and what it is used for

Epanutin is one of a group of medicines called anti-epileptic drugs; this medicine is 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. What you need to know before you take Epanutin

Do not take Epanutin

- if you are allergic to phenytoin, or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other medicines with a similar chemical structure to phenytoin (e.g. hydantoins).

Warnings and precautions

Talk to your doctor or pharmacist before taking 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 anti-epileptics such as phenytoin sodium have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Serious skin side effects can rarely occur during treatment with Epanutin. This risk 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.

Other medicines and Epanutin

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

Some medicines can affect the way Epanutin work and Epanutin itself can reduce the effectiveness of other medicines taken at the same time. These include:

- Medicines used for heart and circulation problems (amiodarone, digoxin, furosemide, reserpine, warfarin, calcium channel blockers e.g. diltiazem, mexiletine, nicardipine, nifedipine, nimodipine, and verapamil)
- Medicines used to lower blood cholesterol, (e.g. atorvastatin, fluvastatin and simvastatin)
  - Medicines used for epilepsy (carbamazepine, lamotrigine, oxcarbazepine, phenobarbital, sodium valproate, topiramate

- and valproic acid, succinimides e.g. ethosuximide and vigabatrin)
- Medicines used to treat fungal infections (e.g. amphotericin B, fluconazole, itraconazole, ketoconazole, miconazole, posaconazole and voriconazole)
  - Medicines used for tuberculosis and other infections (chloramphenicol, clarithromycin, isoniazid, rifampicin, sulphonamides, sulfadiazine, sulfamethoxazole-trimethoprim, doxycycline, ciprofloxacin, efavirenz, fosamprenavir, indinavir, lopinavir/ritonavir, ritonavir and saquinavir)
  - Medicines used for stomach ulcers (omeprazole, sucralfate, the medicines known as H2 antagonists e.g. cimetidine and some antacids)
  - Medicines used for asthma and bronchitis (theophylline)
  - Medicines used for pain and inflammation (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, quetiapine and sertraline)
  - 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 (ciclosporin and tacrolimus)
  - Medicines used for cancer (antineoplastic agents, e.g. bleomycin, capecitabine, carboplatin, cisplatin, doxorubicin, fluorouracil and methotrexate)
  - Muscle relaxants used for surgery (neuromuscular blockers), some anaesthetic drugs (methadone)
  - Some products available without a prescription (folic acid, theophylline, St John's Wort, 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 may also interfere with certain laboratory tests that you may be given.

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 are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you find out you are pregnant, then you should continue to take your medicine until

you have spoken to your doctor for advice. This is because phenytoin should only be used during pregnancy, especially early pregnancy, under the advice of your doctor because it can be harmful to unborn children when taken by a woman during pregnancy. Do not stop taking your medicine until your doctor tells you to.

Breast-feeding

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

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.

Epanutin contain 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

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

Use in children and adolescents

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.

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 are 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 forgotten 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 is the best method 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).
- If you develop a severe skin rash that causes 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). **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. 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.
- 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 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:** 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 anti-epileptic 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 via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Epanutin**

Keep 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 take this medicine after the expiry date which is stated on the carton and bottle label after 'Exp'. The expiry date refers to the last day of that month.  
If the capsules become discoloured or show any signs of deterioration, seek the advice of your pharmacist.  
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. Contents of the pack and other information**

**What Epanutin contains**

The active ingredient in Epanutin is phenytoin sodium.

Each capsule contains 100mg phenytoin sodium.

The other ingredients are: lactose monohydrate, magnesium stearate, and sodium dodecyl sulphate.

The gelatin capsule shells contain erythrosine (E127), quinoline yellow (E104), and titanium dioxide (E171) as colouring agents.

The printing ink contains shellac, black iron oxide (E172) and propylene glycol.

**What Epanutin looks like and contents of the pack**

Epanutin is hard gelatin capsule containing a white powder with a white opaque body and orange cap, radially marked 'EPANUTIN 100', contained in a white plastic container with a white plastic cap.

Each pack contains 100 capsules

**Manufactured by:** Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany.

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

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**POM**

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