

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

EPANUTIN® 100 mg CAPSULES

Phenytoin sodium

Read this leaflet carefully before you start to take EPANUTIN CAPSULES

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- EPANUTIN CAPSULES has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT EPANUTIN CAPSULES CONTAIN

The active ingredient of EPANUTIN CAPSULES is phenytoin sodium. The other ingredients are confectioner's sugar, lactose, magnesium stearate, talc, and the capsule shell contains gelatine.

2. WHAT EPANUTIN CAPSULES ARE USED FOR

EPANUTIN CAPSULES belong to a group of medicines known as anti-epileptic medicines. EPANUTIN CAPSULES can be used to control your epilepsy.

3. BEFORE YOU TAKE EPANUTIN CAPSULES:

Do not take EPANUTIN CAPSULES:

- If you are pregnant, trying to become pregnant, or breastfeeding.
- If you have ever had a reaction (allergic) to phenytoin, phenytoin sodium, EPANUTIN CAPSULES or any of its ingredients, or any other EPANUTIN preparation.
- If you suffer from porphyria. Your doctor will tell you if you suffer from this.
- If you have a family history of Anticonvulsant Hypersensitivity Syndrome (AHS) or if you have been

diagnosed with AHS.

Take special care with EPANUTIN CAPSULES if:

- You are taking any other medicines. There is a list of medicines that EPANUTIN CAPSULES interact with in the next section.
- You drink large amounts of alcohol
- You suffer from liver disease
- A skin rash appears – call your doctor
- You have diabetes
- A small number of people being treated with anti-epileptics such as phenytoin have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- A serious hypersensitivity reaction which is caused by being exposed to certain medicines such as EPANUTIN CAPSULES may occur. This reaction is called drug rash with eosinophilia symptoms (DRESS). The symptoms of this reaction are skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal organs. If you experience any of these symptoms, tell your doctor immediately.

Pregnancy and breastfeeding:

Pregnancy:

EPANUTIN CAPSULES should be avoided if you are pregnant or think you may be unless your doctor considers EPANUTIN CAPSULES to be essential for you.

Breastfeeding:

EPANUTIN CAPSULES must not be taken during breastfeeding.

Ask your doctor or pharmacist for advice before taking EPANUTIN CAPSULES.

Driving and using machinery:

Be advised not to drive a car or operate potentially dangerous machinery until it is known that this medication does not affect your ability to engage in these activities.

Important information about some ingredients of EPANUTIN CAPSULES:

EPANUTIN CAPSULES contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take

EPANUNTIN 100 mg capsules.

Taking other medicines with EPANUTIN CAPSULES:

EPANUTIN CAPSULES sometimes affect the action of other medicines and sometimes EPANUTIN CAPSULES are affected by other medicines. If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of EPANUTIN CAPSULES with these medicines may cause undesirable interactions. Always tell your pharmacist you are taking EPANUTIN when you buy medicines. If you require an operation or will visit your dentist or doctor, let them know that you are taking EPANUTIN.

EPANUTIN CAPSULES may interact with other medicines use to treat:

- Epilepsy (carbamazepine, lamotrigine, phenobarbitone, sodium valproate, valproic acid, succinimides like ethosuximide and vigabatrin)
- Fungal infections (e.g. amphotericin B, fluconazole, itraconazole, ketoconazole and miconazole)
- Tuberculosis and other infections (chloramphenicol, isoniazid, rifampicin, sulphonamides, ciprofloxacin and doxycycline)
- Asthma and bronchitis (theophylline)
- Pain and inflammation (phenylbutazone, salicylates and steroids)
- Stomach ulcers (omeprazole, sucralfate, the medicines known as H₂ antagonists e.g. cimetidine, ranitidine and some antacids)
- Sleeplessness, depression and psychiatric disorders (chlordiazepoxide, clozapine, diazepam, disulfiram, methylphenidate, paroxetine, phenothiazines, trazodone and tricyclic antidepressants)
- Cancer (antineoplastic agents) (fluorouracil and teniposide)
- Heart and circulation problems (amiodarone, reserpine, digitoxin, furosemide, quinidine, warfarin and calcium channel blockers e.g. nifedipine, verapamil)
- Diabetes (tolbutamide)
- Some hormone replacement therapies (oestrogens), oral contraceptives (birth control pills), the anaesthetic agent halothane and some products available without prescription (folic acid, antacids, theophylline, vitamin D, salicylates like aspirin)
- EPANUTIN CAPSULES may also interfere with certain laboratory tests that you may be given
- Excessive alcohol intake can affect the concentration of phenytoin, the active ingredient of

EPANUTIN CAPSULES, in your blood.

4. HOW TO TAKE EPANUTIN CAPSULES:

Always take EPANUTIN CAPSULES exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure. EPANUTIN CAPSULES is to be taken by mouth. Swallow the capsule whole, with plenty of water. Try to take the medicine at the same time every day.

Adults:

The amount of EPANUTIN CAPSULES needed varies from person to person. Most people need between 300 mg – 400 mg a day, taken in three or four equally divided doses. Occasionally higher doses, up to 600 mg daily are needed.

Children:

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 (2 or 3 divided doses a day). The dose is then adjusted up to a maximum of 300 mg a day.

Keep taking EPANUTIN CAPSULES for as long as your doctor instructed you. Do not alter the dose yourself without your doctor's advice. Do not stop taking the capsules unless told to do so by your doctor. If you suddenly stop taking EPANUTIN CAPSULES, you may have a seizure. Should you need to stop taking EPANUTIN CAPSULES your doctor will have decided which is the best method for you.

If you take more EPANUTIN CAPSULES than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you take more EPANUTIN CAPSULES than you should, call your doctor immediately. If you cannot call your doctor, go to the nearest hospital or poison control centre at once. Always take the labelled medicine package with you, whether there is any EPANUTIN CAPSULES left or not. Some symptoms of overdosage include nausea, vomiting, slurred speech, tiredness.

If you forget to take EPANUTIN CAPSULES:

If you forget to take a dose, take it as soon as you remember unless it is time for the next dose. **Do not take two doses at the same time.** If you forget to take EPANUTIN CAPSULES for more than

one week, call your doctor before taking any more medicine.

Do not share medicines prescribed for you with others.

5. POSSIBLE SIDE EFFECTS

Side effects may occur with the use of EPANUTIN CAPSULES.

Not all side effects reported for EPANUTIN CAPSULES are included in this leaflet. **Should your general health worsen or if you experience any untoward effects while taking EPANUTIN CAPSULES, please consult your doctor, pharmacist or other healthcare professional for advice.**

These might include:

- Effects on the *central nervous system* (brain). These include unusual eye movements, unsteadiness, difficulty in controlling movements, shaking, abnormal or uncoordinated movements, slurred speech, confusion, pins and needles or numbness, drowsiness, dizziness or vertigo (dizziness in high places), sleeplessness, nervousness, twitching muscles, headaches, loss of feeling in the hands and feet
- *Skin rash or itchiness*. Many sorts of skin rash have been reported with the use of EPANUTIN CAPSULES. Some are minor (e.g. measles-like or mild dermatitis). Others, although rare, are more serious such as Stevens Johnson Syndrome or toxic epidermal necrolysis (TEN), which cause blistering and can affect the mouth and tongue. Rash may also be a first sign of other side effects of EPANUTIN. If you get a rash, your doctor may advise you to stop taking EPANUTIN CAPSULES until it clears up. If the rash recurs, does not clear up or a serious reaction is suspected, your doctor may advise you not to take EPANUTIN again.
- *Hypersensitivity reaction or syndrome* – Fever, skin rash, swollen glands may occur, usually within the first two months of treatment. Changes in liver function, increased numbers of white blood cells and joint pains may occur as part of this syndrome.

Inflammation in various parts of your body including the joints, skin, kidneys, a condition known as systemic lupus erythematosus, may occur on rare occasions.

Symptoms of a serious hypersensitivity reaction called DRESS include skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal

organs.

- *Swelling of the lymph glands* (a part of your body's natural defence system) and other disorders of the lymph glands may occur. This may be accompanied by fever or rash and may affect your liver but may also be a sign of a problem with your lymph glands.
- *Abnormalities of the blood* including decreases in the number of red cells, white cells or platelets (parts of the blood which help it clot). The first signs you might notice could be bruising, fever, pallor or sore throat. Your doctor may take regular blood samples to test for this.
- Hepatitis (inflammation of the liver) or liver damage which may be recognised by yellowing of the skin and whites of the eyes and changes in liver function.
- Nausea, vomiting, constipation
- Inflammation of the kidneys
- Rare side effects have included: changes in the hands with difficulty in straightening the fingers, changes in facial features, enlarged lips or, enlargement of gums or abnormal body or facial hair, changes in the shape of the penis and painful erection, a condition affecting the joints known as polyarthropathy.
- Increased levels of blood sugar, or decreased levels of blood calcium or folic acid.
- EPANUTIN CAPSULES may alter the amount of vitamin D in your body. 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. Rickets (abnormal development of bone) may occur if this effect is prolonged.

6. STORING AND DISPOSING OF EPANUTIN CAPSULES:

Store all medicines out of reach of children.

Store in a cool (below 25 °C), dry place.

This medicine is for you. Only a doctor can prescribe it for you. Do not share it with anyone else. It may harm them, even if they have the same symptoms as you.

DO NOT use EPANUTIN CAPSULES after the expiry date which is printed on the label. Return all unused medicine to your pharmacist. DO NOT dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF EPANUTIN CAPSULES:

EPANUTIN CAPSULES are available in containers of 100.

8. IDENTIFICATION OF EPANUTIN CAPSULES:

A hard capsule with an orange cap and a white opaque body containing a white powder. The capsule is imprinted with black ink, viz. "PD" on the orange cap and "Dilantin 100 mg" on the white body.

9. REFERENCE NUMBER:

B554 (Act 101/1965)

10. NAME AND ADDRESS OF THE APPLICANT:

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Manufacturer: Pfizer Pharmaceuticals, LLC, Vega Baja, Puerto Rico

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