PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

EPANUTIN® 100 mg Capsules

Phenytoin sodium

Contains sugar

Each capsule contains 57,50 mg lactose monohydrate and 57,20 mg sucrose.

Read all of this leaflet carefully before you start taking EPANUTIN 100 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EPANUTIN 100 mg 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.

What is in this leaflet

1. What EPANUTIN 100 mg is and what it is used for
2. What you need to know before you take EPANUTIN 100 mg
3. How to take EPANUTIN 100 mg
4. Possible side effects
5. How to store EPANUTIN 100 mg
6. Contents of the pack and other information

1. What EPANUTIN 100 mg is and what it is used for

EPANUTIN 100 mg is an anticonvulsant medicine. EPANUTIN 100 mg is used to control your epilepsy.

2. What you need to know before you take EPANUTIN 100 mg

Do not take EPANUTIN 100 mg

- If you are hypersensitive (allergic) to phenytoin or any of the other ingredients of EPANUTIN 100 mg (listed in section 6), or other hydantoin medicines.
- If you suffer from porphyria. Your doctor will tell you if you suffer from this.
- If you are also taking delavirdine (used for HIV therapy).

Warnings and precautions

Take special care with EPANUTIN 100 mg

- If you drink large amounts of alcohol.
- There is a risk of harm to the unborn child if EPANUTIN 100 mg is used during pregnancy. Women of childbearing age should use effective contraception during treatment with EPANUTIN 100 mg (see Pregnancy and breastfeeding).
- A small number of people being treated with anticonvulsants, such as EPANUTIN 100 mg, have had thoughts of harming or killing themselves. If at any time you have these thoughts, contact your doctor immediately.
- A serious allergic reaction which is caused by exposure to EPANUTIN 100 mg may occur. This reaction is called drug reaction with eosinophilia and systemic symptoms (DRESS), and it may be life-threatening or fatal. 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.
- If you have a family history of Hypersensitivity Syndrome (HSS) or DRESS, or if you have been diagnosed with HSS in the past, or if you have a weak immune system.
- Black patients may be at greater risk of liver problems, serious skin reactions and allergic reactions.
- If a skin rash appears, contact your doctor immediately. Potentially life-threatening skin rashes (Stevens-Johnson Syndrome, toxic epidermal necrolysis) have been reported with the use of EPANUTIN 100 mg, 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 eyelids). 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 100 mg, you must not be re-started on EPANUTIN 100 mg at any time. If you develop a rash or these skin symptoms, stop taking EPANUTIN 100 mg, seek urgent advice from a doctor and tell him that you are taking this medicine.

- If you are of Asian ancestry and tests have shown that you carry the genetic variant HLA-B*1502.
- If you suffer from liver disease.
- If you have diabetes.
- If you have or have previously suffered from vitamin D deficiency.
- If you require an operation or visit your dentist or doctor, let them know that you are taking EPANUTIN 100 mg.

Other medicines and EPANUTIN 100 mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

EPANUTIN 100 mg sometimes affects the action of other medicines and sometimes EPANUTIN 100 mg is affected by other medicines.

EPANUTIN 100 mg may interact with other medicines. These include:

- Excessive alcohol intake can affect the concentration of phenytoin, the active ingredient of EPANUTIN 100 mg, in your blood.
- Pain and inflammation: phenylbutazone, salicylates and steroids.
- Anaesthetic medicines: halothane.
- Muscular relaxants used for surgery (neuromuscular blockers): alcuronium, cisatracurium, pancuronium, rocuronium and vecuronium.
- Antibacterial medicines: chloramphenicol, erythromycin and other macrolide antibiotics, isoniazid, sulphamethoxazole-trimethoprim, sulphonamides, ciprofloxacin, rifampicin, doxycycline, tetracycline.
- Medicines used for epilepsy: felbamate, oxcarbazepine, sodium valproate, succinimides, topiramate, vigabatrin, carbamazepine, phenobarbitone, valproic acid, lamotrigine.
- Medicines used for fungal infections: amphotericin B, fluconazole, itraconazole, ketoconazole, miconazole, voriconazole, azoles, posaconazole.
- Medicines used to expel parasitic worms from the body (anthelminthics): albendazole, praziquantel.

- Medicines used for cancer (antineoplastic medicines): capecitabine, fluorouracil, bleomycin, carboplatin, cisplatin, doxorubicin, methotrexate, teniposide.
- Medicines used for stomach ulcers: omeprazole, sucralfate, cimetidine and some antacids.
- Antiretrovirals used for HIV infection treatment: fosamprenavir, nelfinavir, ritonavir, zidovudine, delavirdine, efavirenz, indinavir, lopinavir/ritonavir, saquinavir.
- Medicines used for sleeplessness, depression and psychiatric disorders: chlordiazepoxide, diazepam, disulfiram, methylphenidate, trazodone, viloxazine, phenothiazines, clozapine, paroxetine, quetiapine, sertraline, tricyclic antidepressants, fluoxetine, fluvoxamine.
- Medicines used for asthma and bronchitis: theophylline.
- Medicines used for heart and circulation problems: amiodarone, dicumarol, diltiazem, nifedipine, ticlopidine, reserpine, digoxin, mexiletine, nicardipine, nimodipine, nisoldipine, quinidine, warfarin, verapamil.
- Medicines used to lower high blood cholesterol and triglycerides: atorvastatin, fluvastatin, simvastatin.
- Medicines used for organ and tissue transplants, to prevent rejection: tacrolimus, ciclosporin.
- Medicines used for diabetes: tolbutamide, chlorpropamide, diazoxide, glyburide.
- Some hormone replacement therapies (estrogens), oral contraceptives (birth control pills) and some products available without prescription (folic acid, antacids, vitamin D, salicylates like aspirin and St. John’s Wort).
- Corticosteroids.
- Diuretics: furosemide.
- EPANUTIN 100 mg may also interfere with certain laboratory tests that you may be given.

EPANUTIN 100 mg with alcohol

Drinking alcohol can affect the concentration of phenytoin in your blood. Talk to your doctor or pharmacist for advice.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

EPANUTIN 100 mg should be avoided if you are pregnant or think you may be, or if you are breastfeeding, unless your doctor considers EPANUTIN 100 mg to be essential for you.

EPANUTIN 100 mg use in pregnancy will harm or induce abnormalities in your baby.

EPANUTIN 100 mg crosses into your milk and may harm the baby.

If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with EPANUTIN 100 mg. EPANUTIN 100 mg may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. Talk to your health care provider, who will discuss with you the most suitable type of contraception to use while you are taking EPANUTIN 100 mg.

If you are a woman of childbearing age and are planning a pregnancy, talk to your health care provider before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to EPANUTIN 100 mg.

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

Driving and using machines

It is not always possible to predict to what extent EPANUTIN 100 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EPANUTIN 100 mg affects them.

Do not drive a car or operate potentially dangerous machinery until it is known that EPANUTIN 100 mg does not affect your ability to engage in these activities.

EPANUTIN 100 mg contains lactose monohydrate and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

4. How to take EPANUTIN 100 mg

Do not share medicines prescribed for you with any other person.

Always take EPANUTIN 100 mg exactly as your doctor or pharmacist has told you. Check with your

doctor or pharmacist if you are not sure.

EPANUTIN 100 mg 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 100 mg 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.

Your doctor will tell you how long your treatment with EPANUTIN 100 mg will last. Do not alter the dose yourself without your doctor's advice. Do not stop treatment early because you may have a seizure. Should you need to stop taking EPANUTIN 100 mg, your doctor will decide which the best method is for you.

If you have the impression that the effect of EPANUTIN 100 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more EPANUTIN 100 mg than you should

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

Always take the labelled medicine package with you, whether there is any EPANUTIN 100 mg left or not.

The initial symptoms of overdosage are involuntary eye movement, the loss of full control of bodily movements, and difficulty speaking. Other symptoms of overdosage include tremor, overactive or overresponsive reflexes, tiredness, drowsiness, slurred speech, blurred vision, nausea and vomiting.

If you forget to take EPANUTIN 100 mg

Do not take a double dose to make up for forgotten individual doses. If you forget to take a dose, take it as soon as you remember unless it is time for the next dose. If you forget to take EPANUTIN 100 mg for more than one week, call your doctor before taking any more medicine.

If you stop taking EPANUTIN 100 mg

Treatment with EPANUTIN 100 mg should not be stopped abruptly because of the possibility of increased seizure frequency. If the doctor decides to reduce the dose, stop treatment or change your medicine, this should be done gradually. However, in the event of an allergic or hypersensitivity reaction, rapid substitution of alternative therapy may be necessary.

4. Possible side effects

EPANUTIN 100 mg can have side effects.

Not all side effects reported for EPANUTIN 100 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EPANUTIN 100 mg, please consult your doctor, pharmacist or other health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects

- Confusion, sleeplessness, nervousness.
- Dizziness, unusual eye movements, pins and needles.
- Unsteadiness or difficulty in controlling movements, slurred speech, abnormal or uncoordinated movements, headaches, drowsiness.
- Nausea, vomiting.
- Twitching muscles.

Less frequent side effects

- 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.
- 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.
- Abnormality or difficulty with muscle movement, including jerky involuntary movements, muscular spasm and abnormal posture, shaking, numbness, loss of feeling in the hands and feet. Things may also taste different.
- Vertigo (dizziness in high places).

- Constipation, enlargement of the gums and lips.
- Liver failure which may be fatal, 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.
- 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.
- Skin rash or itchiness: Many sorts of skin rash, sometimes accompanied by fever, have been reported with the use of EPANUTIN 100 mg. 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 100 mg. If you get a rash, your doctor may advise you to stop taking EPANUTIN 100 mg 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 100 mg again.
- 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.
- Abnormal body or facial hair.
- Changes in facial features, inflammation in various parts of your body including the joints, skin, kidneys, a condition known as systemic lupus erythematosus, may occur.
- Changes in the shape of the penis and painful erection (Peyronie's disease).
- Antibody abnormalities.

EPANUTIN 100 mg 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of EPANUTIN 100 mg.

5. How to store EPANUTIN 100 mg

- Store all medicines out of reach of children.
- Store in a cool place, at or below 25 °C.
- Store in the original container.
- Keep the container tightly closed.
- Protect from light and moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EPANUTIN 100 mg contains

- The active substance is phenytoin sodium 100 mg.
- The other ingredients are lactose monohydrate, magnesium stearate, sucrose, talc, and the capsule shell contains gelatine.

What EPANUTIN 100 mg looks like and contents of the pack

Hard, filled No. 3, capsules containing a white powder. The medium orange cap having the “VLE” logo printed in black ink and the white, opaque, body having “DILANTIN” over “100 mg” printed in black ink.

A white, opaque HDPE bottle with a white, polypropylene, child-resistant closure containing 100 capsules.

Holder of Certificate of Registration

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Manufacturer: Viatris Pharmaceuticals LLC, Vega Baja, Puerto Rico

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