1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PHENYTOIN SODIUM 100 mg TABLETS

PHENYTOIN SODIUM CAPSULES

Phenytoin sodium 100 mg

Tablets, capsules

Read all of this leaflet carefully before you start taking PHENYTOIN SODIUM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PHENYTOIN SODIUM 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 PHENYTOIN SODIUM CONTAINS

PHENYTOIN SODIUM CAPSULES

The active substance is phenytoin sodium.

The other ingredients are Calcium Stearate, hydrogenated vegetable oil, lactose monohydrate, macrogol, polyvinyl alcohol (partially hydrolysed), starch maize, talc, titanium dioxide

PHENYTOIN SODIUM 100 mg TABLETS CONTAINS SUGAR: Lactose monohydrate 26,00 mg.

PHENYTOIN SODIUM CAPSULES

The active substance is phenytoin sodium.

The other ingredients are Colloidal silicone dioxide, gelatin, magnesium stearate, pregelatinised starch, sodium lauryl sulphate, talc (purified), titanium dioxide

PHENYTOIN SODIUM CAPSULES: SUGAR FREE.

WHAT PHENYTOIN SODIUM IS USED FOR

PHENYTOIN SODIUM is used for the control of seizures (grand mal) and temporal lobe (psychomotor) epilepsy.

BEFORE YOU TAKE PHENYTOIN SODIUM

Do not take PHENYTOIN SODIUM:

- If you are hypersensitive (allergic) to the active or any of the other ingredients of PHENYTOIN SODIUM. Patients with lactose intolerance should avoid PHENYTOIN SODIUM TABLETS as it contains lactose monohydrate.
- Heart function impairment, such as Adams Stokes syndrome (sudden collapse into unconsciousness due to a disorder of heart rhythm in which there is a slow or absent pulse).
- Sinoatrial block involves an impairment of conduction at the sinoatrial node.
- Sinus bradycardia is heart rhythm in which fewer than the normal number of impulses arise from the sinoatrial (SA) node.
- If you are also taking delavirdine (used for HIV therapy).
- If you have porphyria (an inherited disease that affects the blood).

Take special care with PHENYTOIN SODIUM

- PHENYTOIN SODIUM is not use for all types or seizures, some epilepsy conditions require combined therapy. Some seizures can be aggravated.
- If you have an inherited allelic variant HLA-B*1502 as you are genetically at risk of having serious skin reactions. This allele occurs almost exclusively in patients with ancestry across broad areas of Asia, including South Asian Indians. 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 PHENYTOIN SODIUM. Black patients may be at greater risk of liver problems, serious skin reactions and allergic reactions.
- Abrupt withdrawal of PHENYTOIN SODIUM may cause status

epilepticus (a life-threatening condition in which the brain is in a state of persistent seizure), therefore PHENYTOIN SODIUM should be withdrawn gradually.

- If you are receiving thyroid replacement therapy.
- If you are diabetic.
- If you have porphyria (see Do not take PHENYTOIN SODIUM).
- If you have kidney abnormalities or your levels of albumin in blood serum is abnormally low, associated with AIDS, as the risk of toxicity may be increased.
- Liver disease.
- Alcohol use or dependence.
- If you have had thoughts of harming or killing yourself whilst using PHENYTOIN SODIUM then immediately contact your doctor.
- If any skin rashes or blisters start appearing on your skin. Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of PHENYTOIN SODIUM, 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 PHENYTOIN SODIUM, you must not be re-started on PHENYTOIN SODIUM at any time.
- If you develop a rash or any of these these skin symptoms, stop taking PHENYTOIN SODIUM, seek urgent advice from a doctor and tell him that you are taking this medicine. Consult your doctor before discontinuing PHENYTOIN SODIUM if you

suddenly stop taking this medicine you may have a seizure.

- If you suffer from AHS (Anticonvulsant Hypersensitivity Syndrome, which is a rare medicine induced multiorgan syndrome which is potentially fatal. It presents with fever rash and other organ involvement. Black patients and immunocompromised patients are at higher risk. The other syndromes included are Hypersensitivity Syndrome/Medicine Reaction with Eosinophilia and Systemic Symptoms (HSS/DRESS). You should contact your doctor immediately.
- If you suffer from any blood disorders or immune response disease e.g. Hodgkin's disease (this affects the lymphatic system).
- If you suffer from any central nervous system effects (CNS) as this may be due to levels of the medication being too high and leading to toxicity.
- If you suffer from ulcers, or any stomach pain.
- If you suffer from Vitamin D deficiency.
- If you suffer from seizure due to hypoglycaemia or other metabolic causes, as PHENYTOIN SODIUM is not used.

Taking PHENYTOIN SODIUM with food and drink

PHENYTOIN SODIUM should be taken with half a glassful of water after meals.

Pregnancy and breastfeeding:

The safety of PHENYTOIN SODIUM during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery

Since adverse reactions such as headache, dizziness and visual disturbance have been reported in patients receiving PHENYTOIN SODIUM, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that PHENYTOIN SODIUM does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Important information about some of the ingredients of PHENYTOIN SODIUM

PHENYTOIN SODIUM 100 mg TABLETS contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PHENYTOIN SODIUM 100 mg TABLETS.

PHENYTOIN SODIUM tablets contain lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take PHENYTOIN SODIUM.

PHENYTOIN SODIUM contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.
PHENYTOIN SODIUM CAPSULES are sugar free.

Taking other medicines with PHENYTOIN SODIUM

Always tell your healthcare professional if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- The effects of PHENYTOIN SODIUM may be affected by alcohol intake (chronic or acute alcohol intake).
- Medicines used for heart and circulation problems (e.g. dicoumarol, digitoxin, digoxin, mexiletine, nisoldipine, amiodarone, furosemide, quinidine, reserpine, warfarin, and calcium channel blockers including diltiazem, and nifedipine).
- Medicines used for epilepsy (e.g. carbamazepine, 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, 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).
- Medicines used for organ and tissue transplants, to prevent rejection (e.g. ciclosporin, tacrolimus).
- Medicines used for cancer (antineoplastic medicines such as teniposide, 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 medicines (e.g. halothane, methadone).
- Some products available without a prescription (e.g. folic acid, vitamin D).
- Medicines used for thyroid disorders.
- Your doctor may need to test the amount of PHENYTOIN SODIUM 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 PHENYTOIN SODIUM. If you already take St

John's Wort, consult your doctor before stopping the St John's Wort preparation.

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

HOW TO TAKE PHENYTOIN SODIUM

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

Always take PHENYTOIN SODIUM exactly as your doctor has instructed you.

Your doctor will tell your dose and how long your treatment with PHENYTOIN SODIUM will last.

You should check with your doctor or pharmacist if you are unsure. Do not stop treatment early.

If you have the impression that the effect of PHENYTOIN SODIUM is too strong or too weak, tell your doctor or pharmacist.

If you take more PHENYTOIN SODIUM 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 forget to take PHENYTOIN SODIUM

Take your missed dose as soon as you remember, if within a few hours after missing a dose.

Do not take a double dose to make up for forgotten individual doses

Effects when treatment with PHENYTOIN SODIUM is stopped

Do not stop using PHENYTOIN SODIUM without talking to your doctor first. Do not stop taking PHENYTOIN SODIUM unless your doctor tells you to. If you suddenly stop PHENYTOIN SODIUM you may have a seizure. Should you need to stop taking PHENYTOIN SODIUM, your doctor will decide which is the best method for you.
If you have any further questions on how to take PHENYTOIN SODIUM, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

PHENYTOIN SODIUM can have side effects.

If any of the following happens, stop taking PHENYTOIN SODIUM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching;
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), toxic epidermal necrosis (TEN) or lupus erythematosus (various types or rashes);
- skin rash, fever, swollen glands, including swelling of the lymph glands (particularly in the first two months of treatment), 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).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PHENYTOIN SODIUM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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;
- problems with the body's defence against infection;
- if you experience or have severe mental illness, as this may be a sign that you have high amounts of PHENYTOIN SODIUM in your blood;
- problems or difficulty breathing;
- foetal and infant abnormalities including cleft plate and palate as well as neonatal bleeding;
- impaired heart functions;
- inflammation of the kidneys;
- inflammation of the liver, liver damage or liver failure which can lead to death (seen

as yellowing of the skin and whites of the eye).

Tell your doctor if you notice any of the following:

The following side effects have been frequently reported:

- Hallucinations (seeing or hearing things that are not real);
- feeling sick, being sick, lack of appetite, sore gums;
- pimples and skin rashes or various forms;
- changes in serum levels of proteins and other substances;
- raised serum levels of glucose.

The following side effects have been reported less frequently:

- Blood disorders like anaemia (feeling very tired);
- blurred vision, double vision and unusual eye movements;
- degenaration of the bone;
- 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.

The following side effects have been reported but the frequency is unknown:

- Inflammatory responses;
- Constipation;
- headache, dizziness, tremor, nervousness;
- high sugar levels;
- elevated alkaline phosphatase;

- hypotension (low blood pressure);
- effects on medical tests: decreased levels of blood calcium, phosphate, 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 and muscle pain or fractures;
- decrease in libido and fertility in male ;
- male breasts;
- 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;
- unsteadiness, difficulty in controlling movements, shaking, abnormal or uncoordinated movements, slurred speech, confusion, pins and needles or numbness, drowsiness, vertigo, sleeplessness, nervousness, twitching muscles, and change in taste;
- effects on your reproductive system: changes in the shape of the penis, painful erection.

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

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: https://www.sahpra.org.za/Publications/Index/8.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088 / +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of PHENYTOIN.

STORAGE AND DISPOSING OF PHENYTOIN SODIUM

Store at or below 25 °C.

Store all medicines out of reach of children.

Store in airtight containers.

Do not store in bathrooms.

Keep in original packaging until required for use.

Do not use PHENYTOIN SODIUM after the expiry date which is 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).

PRESENTATION OF PHENYTOIN SODIUM

PHENYTOIN SODIUM 100 mg Tablets:

90, 500 or 1 000 tablets are packed in a white polypropylene container with a white linear low density polyethylene snap-on cap, together with a foam or rayon insert and a leaflet.

5 000 tablets are packed in a high density polyethylene bucket lined with a polyethylene bag or, alternatively, into a 2,5 l metal tin lined with a polyethylene bag, together with a leaflet.

84 tablets are packed in a patient ready pack in Ziploc lay-flat bags or metalised lay-flat bags. These packed bank bags are grouped, packed and sealed into polyethylene bags together with a leaflet.

PHENYTOIN SODIUM CAPSULES

100 capsules are packed in a white polypropylene securitainer with a white, low density polyethylene snap-on cap, together with a dessicant disc and leaflet.

1 000 capsules are packed in an amber polyvinyl chloride xactic container with a high density polyethylene screw cap, together with a silica gel sachet and a leaflet.

84 capsules are packed into pre-printed low density polyethylene Ziploc lay-flat or metallocene lay-flat bags.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF PHENYTOIN SODIUM

PHENYTOIN SODIUM 100 mg Tablets: A white, round, shallow biconvex film-coated tablet free from cracking, peeling and chipping.

PHENYTOIN SODIUM CAPSULES: A white No 3 opaque gelatin capsule containing a white powder.

REGISTRATION NUMBER

PHENYTOIN SODIUM 100 mg Tablets: B884 (ACT 101/1965)

PHENYTOIN SODIUM CAPSULES: B0885 (ACT 101/1965)

NAME AND ADDRESS OF REGISTRATION HOLDER

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