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. What is in this leaflet 1. What Phenytoin Milpharm tablets are and what they are used for 2. What you need to know before you take Phenytoin Milpharm tablets 3. How to take Phenytoin Milpharm tablets 4. Possible side effects 5. How to store Phenytoin Milpharm tablets 6. Contents of the pack and other information

1. What Phenytoin Milpharm tablets are and what they are used for

The name of your medicine is Phenytoin Sodium Milpharm 100 mg film-coated tablets (referred to as Phenytoin tablets or as Phenytoin throughout this leaflet).

Phenytoin is one of a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy. Phenytoin tablets can be used to control a variety of epileptic conditions (tonic-clonic seizures and partial seizures), to prevent or prevent seizures during or after brain surgery or severe head injury. Phenytoin 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 Phenytoin tablets.

Note: Phenytoin sodium is not effective in absence seizures or in the prophylaxis and treatment of febrile convulsions.

2. What you need to know before you take Phenytoin Milpharm tablets

Do not take Phenytoin tablets

• 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. hydantoin).

Warnings and precautions

Talk to your doctor or pharmacist before taking Phenytoin sodium. Medicines are not always suitable for everyone. Your doctor needs to know before you take phenytoin if you suffer from or have suffered in the past from any of the following conditions:

- liver disease
- kidney disease
- Porphyria (an inherited disease that affects haemoglobin biosynthesis)

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.

Phenytoin may precipitate or aggravate certain forms of epilepsy (absence seizures and myoclonic seizures).

A small number of people being treated with antiepileptic drugs 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 Phenytoin Tablets, appearing initially as reddish targets or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitains 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, stop using Phenytoin Tablets, you must not be re-started on Phenytoin Tablets at any time.

If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Serious skin side effects can rarely occur during treatment with phenytoin. 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 (HALB* 1502), discuss this with your doctor before taking Phenytoin Tablets.

You should be administered phenytoin with caution if you suffer from kidney or liver problems.

Black patients may be at greater risk of liver problems. Serious skin reactions and allergic reactions to other medicines

Some medicines can affect the way Phenytoin works, or Phenyltoin 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, and calcium channel blockers e.g. diltiazem, mexiletine, nicardipine, nifedipine, nilidine, dicypramide and verapamil).
- Medicines used to lower blood cholesterol, (e.g. atorvastatin, fluvastatin and simvastatin).
- Medicines used for epilepsy (carbamazepine, lamotrigine, sodium valproate and valproic acid, succinimides e.g. ethosuximide and vigabatrin).
- Medicines used to treat fungal infections (e.g amphotericin B, fluconazole, itraconazole, ketoconazole, micafungin, voriconazole and voriconazole).
- Medicines used for tuberculosis and other infections (chloramphenicol, isoniazid, rifampicin, sulphonamides, doxycycline, clarithromycin, sulfadiazine, sulfamethoxazole-trimethoprim, ofloxacin, rifavirin, isosparfamide, indinavir, ketoprofen, 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 (salsalicyl e.g. aspirin and steroids).
- Medicines used to expel parasitic worms (helminths) from the body (anthelmintics).
- Medicines used for sleeplessness, depression and psychiatric disorders (chloralhydrate, clozapine, diazepam, disulfiram, fluoxetine, methylphenidate, paroxetine, phenothiazines, trazodone, tricyclic antidepressants, fluvanamine, quetiapine and sertraline).
- Medicines used for diabetes (biguanides).
- 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 (anti-cancer agents) e.g: bleomycin, capetarbiniel, carboplatin, cisplatin, doxorubicin, fluorouracil and methotrexate).
- Muscule relaxants used for surgery (neuromuscular blockers like Pancuronium, Rocuronium, Vecuronium), some anaesthetic drugs (methohexitone).
- Some products available without a prescription (tolic 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.

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

Phenytoin with food, drink and alcohol

Phenytoin tablets 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 may 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, occasionally during breast-feeding, under the strict advice of your doctor because it can be harmful to unborn children when taken by a woman expecting pregnancy. Do not stop taking your medicine until your doctor tells you to.

Breast-feeding

You should not take Phenytoin tablets if you are breast-feeding.

Driving and using machines

Phenytoin 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 machines that require alertness.

Phenytoin Tablets Contains Sodium.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.
If you suddenly stop taking this medicine you may have a seizure. Do not stop taking Phenytoin tablets unless your doctor tells you to. Do not take a double dose to make up for a forgotten dose. If you stop taking Phenytoin tablets Do not take Phenytoin tablets unless your doctor tells you to. If you suddenly stop taking this medicine you may have a seizure. Should you need to stop taking Phenytoin tablets, your doctor will decide which method is best for you. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

• 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, phosphate, folie acid and vitamin D and abnormal thyroid function test results. 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 and immunoglobulin abnormalities.
• 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 osteopenia, or take steroids.

Additional side effects that can occur in children The adverse event profile of phenytoin is generally similar between children and adults. Swollen gums occur more frequently in paediatric patients and in patients with poor oral hygiene.

5. Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Your can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

6. Contents of the pack and other information

What Phenytoin tablets contain The active substance is Phenytoin sodium. Each film-coated tablet contains 100 mg of phenytoin sodium.
• The other ingredients are

Tablet coat:
• Hypromellose
• Magnesium stearate
• Croscarmellose sodium
• Sodium lauryl sulphate

What Phenytoin tablets look like and contents of the pack Whole milk or full-fat cow’s milk. All liquid milk based tablets debossed with “C” on one side and “70” on the other side.

PolyvinylAluminium/PVC/Celaluminium blister pack: 10, 14, 20, 28, 30, 50, 60, 84, 100, 112, 200 and 250 film-coated tablets

HDPE container with a polypolyethylene closure and silica gel desiccant:
30 film-coated tablets.

Not all pack sizes may be marketed.

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