

## PHENYTOIN SODIUM TEVA 100 mg TABLETS

### PACKAGE LEAFLET: INFORMATION FOR THE USER

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

## 1 WHAT PHENYTOIN SODIUM IS AND WHAT IT IS USED FOR

- Phenytoin Sodium is an anticonvulsant.
- Phenytoin Sodium is used:
  - to control or prevent seizures (fits)
  - to treat trigeminal neuralgia (severe stabbing pain on one side of the face affecting the forehead, cheek, lips, gums or chin)
  - for the prevention or control of seizures during or following neurosurgery and/or head injury.

## 2 WHAT YOU NEED TO KNOW BEFORE YOU TAKE PHENYTOIN SODIUM

**Do NOT take Phenytoin Sodium:**

- If you are allergic (hypersensitive) to Phenytoin Sodium or any of the other ingredients of this medicine
- If you have a known allergy (hypersensitivity) to hydantoin (a group of antiepileptic drugs)

**Take special care with Phenytoin Sodium Warnings and precautions**

**-There is a risk of harm to the unborn child if Phenytoin Sodium is used during pregnancy. Women of childbearing age should use effective contraception during treatment with Phenytoin Sodium (see Pregnancy and breast-feeding).**

**-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.**

**-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 Phenytoin Sodium. This risk may be associated with a variant in genes in a subject of Chinese or Thai origin. If you are of such origin and have been tested positively carrying this genetic variant (HLA-B\*1502), discuss this with your doctor before taking Phenytoin Sodium.**

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

Talk to your doctor before taking Phenytoin Sodium if you

- are diabetic
- are pregnant or planning to become pregnant.
- have liver or kidney problems
- suffer from petit mal fits as you may need additional medicine to control your fits
- have low blood pressure
- are suffering from fever, rash, swelling of glands and liver disease after starting this medicine
- have skin rash, fever, blistering on skin immediately contact your doctor. Treatment may be discontinued in these cases.
- are being treated for alcohol addiction (e.g. taking disulfiram)
- have a rare hereditary problem of galactose intolerance or Lapp lactose deficiency.
- suffer from intermittent porphyria (a deficiency of specific enzymes within the body, causing an increase of substances called porphyrins)
- are of Taiwanese, Japanese, Malaysian or Thai origin and tests have shown that you carry the genetic variant CYP2C9\*3.

Phenytoin may cause or aggravate absence seizures and myoclonic seizures.

If you are to undergo surgery you should ensure that your doctor and the anaesthetist are aware you are taking Phenytoin Sodium, as it may interact with halothane and lidocaine (anaesthetics).

Your doctor will be carrying out regular blood and urine tests particularly at the start of your treatment and every month afterwards. These may include blood glucose tests and tests to check your liver is working properly, as well as tests to see how much phenytoin is in your blood.

Phenytoin Sodium can affect the results of other blood tests you may have; make sure the doctor knows you are taking Phenytoin Sodium if you have any other blood tests.

If you are taking Phenytoin Sodium for a long period of time your doctor may recommend the use of Vitamin D supplements to prevent rickets or osteomalacia (softening and weakening of the bones).

If you are taking Phenytoin Sodium your doctor may recommend the use of folic acid (vitamin B) supplements.

If you see another doctor or go into hospital, let the staff know what medicines you are taking.

**Other medicines and Phenytoin Sodium Do NOT take Phenytoin Sodium in combination with:**

- the herbal remedy, St John's Wort (Hypericum perforatum). If you already take St John's Wort, talk to your doctor before stopping the St John's Wort preparation.

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following:**

- other medicines for treatment of epilepsy e.g. carbamazepine, lamotrigine, tiagabine, zonisamide, oxcarbazepine, valproate, primidone, topiramate, succinimides e.g. ethosuximide, and vigabatrin
- medicines for treatment of fungal infections, such as voriconazole, caspofungin, fluconazole, itraconazole, ketoconazole and miconazole
- anti-malarial medicines such as chloroquine, hydroxychloroquine, mefloquine and pyrimethamine
- medicines to thin the blood known as coumarins e.g. warfarin
- anticoagulants e.g. rivaroxaban, dabigatran, apixaban, edoxaban
- lacosamide
- ticagrelor
- isoniazid and rifamycins (such as rifampicin) used to treat tuberculosis
- antibiotics for treatment of infections such as chloramphenicol, sulphonamides, doxycycline, ciprofloxacin, clarithromycin, metronidazole, telithromycin, or trimethoprim
- theophylline for asthma and bronchitis
- diazoxide, eplerenone and carbonic anhydrase inhibitors e.g. acetazolamide for high blood pressure
- corticosteroids, aspirin, leflunomide or steroids for pain and inflammation
- medicines for treatment of stomach ulcers such as some antacids, omeprazole, esomeprazole, sucralfate, and medicines known as H<sub>2</sub> antagonists e.g. cimetidine
- medicines known as 5HT<sub>2</sub> antagonists e.g. ondansetron or aprepitant, used to treat nausea
- medicines for treating psychiatric disorders such as clozapine, phenothiazines, aripiprazole, quetiapine, sertindole, or lithium
- medicines known as benzodiazepines such as diazepam, clonazepam, chlordiazepoxide
- medicines for treatment of depression known as MAOIs such as moclobemide and phenelzine
- medicines for treatment of depression known as SSRIs such as fluoxetine, sertraline, fluvoxamine, paroxetine
- other antidepressant medicines such as trazodone, mianserin, and mirtazapine
- methylphenidate for treating behavioural disorders
- modafinil for treating sleep disorders
- fluorouracil, methotrexate, etoposide, imatinib and levetiracetam for cancer
- bupropion for smoking addiction
- ciclosporins to prevent rejection of organ and tissue transplants
- medicines for heart problems such as dicoumarol, amiodarone, reserpine, digoxin, digoxin, furosemide, quinidine, disopyramide, mexiletine, felodipine, isradipine, verapamil, nisoldipine, dihydropyridines, nicardipine or calcium channel blockers e.g. diltiazem and nifedipine
- tolbutamide for diabetes
- fluvastatin for high cholesterol
- disulfiram for alcohol abuse
- levodopa for Parkinson's disease
- sulfipyrazole, phenylbutazone for gout and arthritis
- medicines for the treatment of HIV infection such as abacavir, amprevir, indinavir, lopinavir, saquinavir, nelfinavir and zidovudine
- tibolone, thyroid hormones, enteral foods, influenza vaccine, phenobarbital.

Phenytoin Sodium may also interact with some hormone replacement therapies (oestrogens), progestogen (contraceptive pill), other oral contraceptives (the birth control pill), and toremifene, gestrinone, the anaesthetic agent halothane, muscle relaxants used for surgery (neuromuscular blockers), methadone and some products available without a prescription (folic acid, antacids, theophylline, vitamin D, salicylates e.g. aspirin).

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Phenytoin sodium with food, drink and alcohol**

Phenytoin 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, breast-feeding and fertility**

**What you should know about the use of antiepileptic drugs in pregnancy**

If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.

If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.

You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy is well controlled.

Taking phenytoin during pregnancy increases the chance that the baby may have a physical birth abnormality.

Studies with women treated with phenytoin for epilepsy during pregnancy have shown that around 6 babies in every 100 will have serious physical birth abnormalities. This compares to 2-3 babies in every 100 born to women who don't have epilepsy.

The most common types of serious physical birth abnormalities (major congenital malformations) reported for phenytoin include abnormalities of the lip and palate, heart, skull, nail and finger disorders and growth abnormalities. Some of these may occur together as part of a fetal hydantoin syndrome.

Taking more than one epilepsy medicine at the same time may also increase the risk of physical birth abnormalities. Where possible, your doctor will consider using one epilepsy medicine only to control your epilepsy.

Your doctor may advise you to take folic acid if you're planning to become pregnant and while you're pregnant. Your doctor may adjust your epilepsy medicine when you take folic acid.

Some studies observed that taking phenytoin during pregnancy increases the chance that the baby may have problems affecting

<p>learning and thinking abilities.</p> <p>Phenytoin Sodium can cause major birth defects. If you take Phenytoin Sodium during pregnancy your baby has up to 3 times the risk of having a birth defect than women not taking an antiepileptic medication. Major birth defects including growth, skull, facial, nail, finger and heart abnormalities have been reported.</p> <p>Some of these may occur together as part of a foetal hydantoin syndrome.</p> <p>Problems with neurodevelopment (development of the brain) have been reported in babies born to mothers who used phenytoin during pregnancy. Some studies have shown that phenytoin negatively affects neurodevelopment of children exposed to phenytoin in the womb, while other studies have not found such an effect. The possibility of an effect on neurodevelopment cannot be ruled out.</p> <p>If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with Phenytoin Sodium. Phenytoin Sodium may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking Phenytoin Sodium.</p> <p>If you are a woman of childbearing age and are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to phenytoin.</p> <p>If you are or think you might be pregnant, tell your doctor straight away. You should not stop taking your medicine until you have discussed this with your doctor. Stopping your medication without consulting your doctor could cause seizures which could be dangerous to you and your unborn child. Your doctor may decide to change your treatment. Phenytoin is not recommended if you are breast-feeding.</p> <p><b>Driving and using machines</b></p> <p>Phenytoin Sodium 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.</p> <p><b>Phenytoin Sodium contains sucrose</b></p> <p>Patients who are intolerant to sucrose should note that Phenytoin tablets contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.</p>	<p>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.</p> <ul style="list-style-type: none"> <li>• 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 (parts of the blood which help it to clot). Your doctor may take regular blood samples to test for these effects.</li> </ul> <p>The following side effects have been reported:</p> <ul style="list-style-type: none"> <li>• unusual eye movements, unsteadiness, difficulty in controlling movements, abnormal or uncoordinated movements, shaking, wrist shaking, slurred speech, aggressive behaviour, confusion, abnormal skin sensation, nervousness, memory problems, double vision, depression, fits, pins and needles or numbness, twitching muscles, loss of feeling in the hands or feet, drowsiness, dizziness or vertigo (a feeling of dizziness or "spinning"), sleeplessness, taste perversion, tiredness malfunction of nerves in different parts of the body simultaneously</li> <li>• headaches</li> <li>• swelling of the lymph glands (a part of your body's natural defence system)</li> <li>• inflammation of the wall of the arteries, enlargement of spleen and liver,</li> <li>• hepatitis (inflammation of the liver) or liver damage which may be recognised by yellowing of the skin and whites of the eyes</li> <li>• feeling sick, being sick, constipation</li> <li>• inflammation of the kidneys</li> <li>• breathing problems, mainly inflammation of the lining of the lung</li> <li>• changes in the hands with difficulty in straightening the fingers, thickening of tissues in the palm</li> <li>• changes in facial features, enlarged lips or gums</li> <li>• increased or abnormal body or facial hair</li> <li>• changes in the shape of the penis and painful erection</li> <li>• a condition affecting your joints known as polyarthropathy</li> <li>• bleeding, tender or enlarged gums (may be reduced by maintaining good oral hygiene and massaging the gums)</li> <li>• a decrease in the number of a type of red blood cell (pure red cell aplasia).</li> </ul> <p>Phenytoin Sodium Tablets may alter the amount of vitamin D in your body and decrease levels of blood calcium, phosphate 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. Rickets (abnormal development of bone) may occur if this effect is prolonged.</p> <p>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. Inflammation of the walls of the arteries and problems with the body's defence against infection (the immune system) has also been seen.</p> <p>When extremely high amounts of phenytoin are in the blood, extreme confusion sometimes referred to as delirium, psychosis or encephalopathy (a brain disease) has been reported. On rare occasions, when the amount of phenytoin in the blood has remained high for a long time, irreversible brain injury has occurred.</p> <p>If you are elderly, or have kidney or liver disease, you may experience these side effects at lower doses of Phenytoin Sodium than otherwise.</p>
<p><b>3 HOW TO TAKE PHENYTOIN SODIUM</b></p> <p>Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.</p> <p>The recommended dose is:</p> <ul style="list-style-type: none"> <li>• <b>Adults including the Elderly:</b> <ul style="list-style-type: none"> <li>100 mg taken 2 to 4 times a day but this will be adjusted to suit you.</li> <li>The usual maintenance dose is 200 to 500 mg daily in divided doses.</li> <li>Patients with reduced liver or kidney function may be given a lower dose.</li> </ul> </li> <li>• <b>Infants and children:</b> <ul style="list-style-type: none"> <li>The doctor will calculate the appropriate dose of Phenytoin Sodium for your child based on the child's body weight.</li> <li>The maximum daily dose is 300 mg.</li> </ul> </li> <li>• <b>Newborn children:</b> <ul style="list-style-type: none"> <li>The doctor will monitor your child and determine the appropriate dose of Phenytoin.</li> </ul> </li> </ul> <p>The tablets should be swallowed preferably with a glass of water.</p> <p><b>If you take more Phenytoin Sodium than you should</b></p> <p>If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause involuntary movements of the eyes, difficulty in controlling movements, slurred speech, coma, fixed enlarged pupils, low blood pressure, breathing problems and high levels of sugar in the blood. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.</p> <p><b>If you forget to take Phenytoin Sodium</b></p> <p>If you forget to take your medicine, take it as soon as you remember, unless it is nearly time to take the next dose. Do not take a double dose to make up for a forgotten dose.</p> <p><b>If you stop taking Phenytoin Sodium</b></p> <p>Do not stop taking your medicine without talking to your doctor first even if you feel better.</p> <p>Do not stop taking Phenytoin suddenly as this may cause fits. Your dose should be reduced gradually.</p> <p>If you have any further questions on the use of this medicine, ask your doctor or pharmacist.</p>	<p><b>Reporting of side effects:</b></p> <p>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: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> 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.</p> <p><b>5 HOW TO STORE PHENYTOIN SODIUM</b></p> <p><b>Keep this medicine out of the sight and reach of children.</b></p> <p>Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.</p> <p>Store below 25°C. Store in the original package.</p> <p>Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.</p>
<p><b>4 POSSIBLE SIDE EFFECTS</b></p> <p>Like all medicines, this medicine can cause side effects, although not everybody gets them.</p> <p>If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital. Although following side effects are very rare, these symptoms can be serious.</p> <ul style="list-style-type: none"> <li>• an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)</li> <li>• potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2), which causes blistering and can affect the mouth and tongue.</li> </ul> <p>Your doctor may advise you to stop taking Phenytoin Sodium Tablets until it clears up. If the rash does not clear up or a serious reaction is suspected, your doctor may advise you not to take phenytoin sodium again.</p> <ul style="list-style-type: none"> <li>• hypersensitivity syndrome has been reported, the symptoms of which include inflammation in the joints, skin rash, fever, swollen glands and liver problems. A condition known as systemic lupus erythematosus may occur on rare occasions. A rash may be the first sign of this condition but it may also be noticed as fever, pain in the joints and general ill health. Although still rare, you may be more likely to get this syndrome, skin rash or liver damage, if you are black.</li> <li>• 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</li> </ul>	<p><b>6 CONTENTS OF THE PACK AND OTHER INFORMATION</b></p> <p><b>What Phenytoin Sodium Teva tablets contain:</b></p> <ul style="list-style-type: none"> <li>• The active ingredient has 100 mg of phenytoin sodium.</li> <li>• The other ingredients are calcium hydrogen phosphate dihydrate, sucrose (icing sugar), sucrose, purified water and magnesium stearate (E572). The coating consists of gelatin, sucrose, talc, shellac (E904), beeswax (E901), carnauba wax (E903) and the colour, titanium dioxide (E171). The printing ink contains shellac, black iron oxide (E172) and propylene glycol (E1520).</li> </ul> <p><b>What Phenytoin Sodium Teva tablets look like and contents of the pack:</b></p> <ul style="list-style-type: none"> <li>• Phenytoin Sodium 100 mg Tablets are white coated tablets with APS or plain on one side and 100/2302 on the reverse.</li> <li>• The product is available in pack sizes of 7, 10, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168 and 500. See outer packaging or the pharmacy label for contents i.e. the number of tablets. Not all pack sizes may be marketed.</li> </ul> <p><b>Marketing Authorisation Holder</b></p> <p>Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom</p> <p><b>Manufacturer</b></p> <p>TEVA Pharmaceutical Works Private Limited Company, Pallagi street 13, Debrecen, H-4042, Hungary.</p> <p><b>This leaflet was last revised in June 2023</b></p> <p>PL 00289/5236R</p>