

Package leaflet: Information for the patient

Phenytoin Sodium NRI 100mg Capsules

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.
- The full name of this medicine is Phenytoin Sodium NRI 100mg Capsules but within the leaflet it will be referred to as Phenytoin Capsules.

What is in this leaflet:

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

1. What Phenytoin Capsules are and what they are used for

Phenytoin Capsules contain phenytoin which belongs to a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy.

Phenytoin Capsules can be used to control a variety of epileptic conditions, to control or prevent seizures during or after brain surgery or severe head injury. Phenytoin Capsules 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 Capsules.

2. What you need to know before you take Phenytoin Capsules

Do not take Phenytoin Capsules if you:

- are **allergic** to phenytoin, other hydantoin products or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Phenytoin Capsules, especially 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).
- If you are of Taiwanese, Japanese, Malaysian or Thai origin and tests have shown that you carry the genetic variant CYP2C9*3.

The following symptoms have been reported in some people treated with phenytoin at recommended doses:

- shortness of breath, becoming unconscious, or unresponsive. All can be symptoms of the sudden, unexpected stopping of the heart (known as cardiac arrest). If you or someone you know is taking Phenytoin Capsules and experiencing these symptoms, **seek immediate medical support**.
- slower heartbeat (known as bradycardia).

A small number of people being treated with antiepileptics 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 Capsules, 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 and genitals or conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms, including fever at the initiation of treatment. 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 Capsules, you must not be re-started on Phenytoin Capsules at any time.

If you develop a rash or these skin symptoms, stop taking Phenytoin Capsules, seek urgent advice from a doctor and tell them that you are taking this medicine. Talk to your doctor before permanently discontinuing Phenytoin Capsules. If you suddenly stop taking this medicine, you may have a seizure.

Talk to your doctor before taking Phenytoin Capsules if you are of Taiwanese, Japanese, Malaysian or Thai origin and tests have shown that you carry the genetic variant CYP2C9*3.

Serious skin side effects can rarely occur during treatment with Phenytoin Capsules. 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 (HLA-B*1502), discuss this with your doctor before taking Phenytoin Capsules.

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

Other medicines and Phenytoin Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can affect the way Phenytoin Capsules work or Phenytoin Capsules themselves 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, ticagrelor, warfarin, calcium channel blockers e.g. diltiazem, mexiletine, nifedipine, nifedipine, nimodipine, disopyramide and verapamil).
- Medicines used to lower blood cholesterol (e.g. atorvastatin, fluvastatin and simvastatin)
- Medicines used for epilepsy (carbamazepine, lamotrigine, oxcarbazepine, phenobarbital, sodium valproate, topiramate and valproic acid, succinimides e.g. ethosuximide and vigabatrin, lacosamide).
- Medicines used to treat fungal infections (e.g. amphotericin B, fluconazole, itraconazole, ketoconazole, miconazole, posaconazole and voriconazole).
- Medicines used for tuberculosis and other infections (chloramphenicol, clarithromycin, isoniazid, rifampicin, sulfonamides, sulfadiazine, sulfamethoxazole-trimethoprim, doxycycline, ciprofloxacin, efavirenz, fosamprenavir, indinavir, lopinavir/ritonavir, ritonavir and saquinavir).
- Medicines used for stomach ulcers (omeprazole, sucralfate, medicines known as H₂ antagonists e.g. cimetidine and some antacids).
- Medicines used for asthma and bronchitis (theophylline).
- Medicines used for pain and inflammation (salicylates e.g. aspirin and steroids).
- Medicines used for sleeplessness, depression and psychiatric disorders (chlordiazepoxide, clozapine, diazepam, disulfiram, fluoxetine, methylphenidate, paroxetine, phenothiazines, trazodone, tricyclic antidepressants, fluvoxamine, quetiapine and sertraline).
- Medicines used for diabetes (tolbutamide).
- Some hormone replacement therapies (oestrogens), oral contraceptives (the birth control pill).
- Medicines used for organ and tissue transplants, to prevent rejection (cyclosporin and tacrolimus).
- Medicines used for cancer (antineoplastic agents e.g. bleomycin, capecitabine, carboplatin, cisplatin, doxorubicin, fluorouracil and methotrexate).
- Muscle relaxants used for surgery (neuromuscular blockers), some anaesthetic drugs (methadone).
- Medicines used for the treatment of parasitic worms (anthelmintics).
- Medicines used as anticoagulants (e.g. rivaroxaban, dabigatran, apixaban, edoxaban).
- Some products available without a prescription (folic 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 Capsules may also interfere with certain laboratory tests that you may be given.

Phenytoin Capsules with food, drink and alcohol

Phenytoin Capsules 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.

Pregnancy, contraception in women, breast-feeding Pregnancy

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.

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 are planning to become pregnant and while you are 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 learning and thinking abilities.

If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with Phenytoin Capsules. Phenytoin Capsules 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 Capsules.

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.

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. Closer monitoring of your unborn child could also be considered.

If you take Phenytoin Capsules during pregnancy, your baby is also at risk of bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this. Moreover, your child should be closely monitored.

Breast-feeding

Phenytoin passes into breast milk. You should not take Phenytoin Capsules if you are breast-feeding.

Driving and using machines

Phenytoin Capsules may cause dizziness or drowsiness, especially during the first few weeks of treatment. If you experience these symptoms, do not drive or operate tools or machinery.

Phenytoin Capsules contain lactose

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

Information on sodium content

This medicine contains less than 1 mmol sodium (23mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Phenytoin Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It is best to take Phenytoin Capsules at the same time each day. Swallow the capsules whole, with plenty of water.

Adults

The number of Phenytoin Capsules needed varies from one person to another. Most adults need between 200mg and 500mg a day either as a single or divided dose. Occasionally higher doses are needed.

Children and adolescents

Infants and children usually start on a dose that depends on their weight (5mg per day for every kg they weigh) and is given as a divided dose, twice a day. The dose is then adjusted up to a maximum of 300mg a day.

Elderly and patients with kidney or liver disease

The dose of Phenytoin Capsules for elderly patients, patients with kidney or liver disease, or those who may be taking other medicines may also need careful consideration and adjustment by their doctor.

If you take more Phenytoin Capsules than you should

Phenytoin Capsules are dangerous in overdose. If you or someone else accidentally take too many Phenytoin Capsules, contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there are any Phenytoin Capsules left or not.

If you forget to take Phenytoin Capsules

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Phenytoin Capsules

Do not stop taking Phenytoin Capsules 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 Capsules, your doctor will have decided which is the best method for you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following serious side effects after taking this medicine:

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- If you develop a severe skin rash that causes blistering (this can also affect the mouth and tongue). These may be signs of a condition known as Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). **Your doctor will stop your treatment in these cases.**

- 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 a decrease in the number of red blood cells, white blood cells or platelets, or a decrease in the number of a type of red blood cell (pure red cell aplasia). Your doctor may take regular blood samples to test for these effects.
- If you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters. These may be signs of a condition known as acute generalised exanthematous pustulosis (AGEP). The frequency of this side effect is not known (cannot be estimated from available data).
- Skin rash and fever with swollen glands, particularly in the first two months of treatment, as these may be signs of a hypersensitivity reaction. If these are severe and you also experience pain and inflammation of the joints this could be related to a condition called systemic lupus erythematosus.
- 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 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.

Other side effects that may occur are:

- Unusual eye movements, unsteadiness, difficulty in controlling movements, shaking, abnormal or uncoordinated movements, slurred speech, confusion, pins and needles or numbness, drowsiness, dizziness, vertigo, sleeplessness, nervousness, twitching muscles, headaches and taste change.
- Skin rash including measles-like reactions which are mild.
- Feeling sick, being sick and constipation.
- Swelling of the lymph glands.
- A decrease in the number of a type of red blood cell (pure red cell aplasia).
- Inflammation of the kidneys and liver, liver damage (seen as yellowing of the skin and whites of the eye).
- Changes in the shape of the penis, painful erection.
- 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.
- Increased levels of blood sugar, or decreased levels of blood calcium, phosphate, folic 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.
- Problems breathing, inflammation of the lining of the lung.
- Problems with the body's defence against infection, inflammation of the wall of the arteries.
- 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.

Reporting of side effects

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 Website: 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.

5. How to store Phenytoin Capsules

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date, which is stated on the carton and also on the bottle label. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package. Keep the container tightly closed in order to protect from light and moisture.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Phenytoin Capsules contain

The active substance in this medicine is phenytoin sodium. Each hard capsule contains 100mg phenytoin sodium.

The other ingredients are lactose monohydrate and magnesium stearate.

The capsule shell is made of gelatin, water, erythrosine (E127), quinoline yellow (E104), titanium dioxide (E171), sodium lauryl sulfate and black edible printing ink, which contains shellac, propylene glycol, black iron oxide (E172) and potassium hydroxide.

What Phenytoin Capsules look like and contents of the pack

Phenytoin sodium NRIM 100mg Capsules are size '3', hard gelatin capsules with an orange transparent coloured cap printed with "146" and white coloured body, containing white granular powder.

Phenytoin sodium NRIM 100mg Capsules are supplied in a HDPE capsule container with a child-resistant polypropylene cap. Each bottle contains 84 capsules.

Marketing Authorisation Holder and Manufacturer

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If you would like a leaflet with larger text, please contact +44 (0) 1271 385257