

PHENYTOIN SODIUM NRIM 100MG CAPSULES

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Phenytoin Capsules are and what they are used for
2. Before you take Phenytoin Capsules
3. How to take Phenytoin Capsules
4. Possible side effects
5. How to store Phenytoin Capsules
6. Further Information

1. WHAT PHENYTOIN CAPSULES ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Phenytoin sodium NRIM 100mg Capsules (referred to as Phenytoin Capsules or as Phenytoin throughout this leaflet).

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

Phenytoin 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 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. BEFORE YOU TAKE PHENYTOIN CAPSULES

You should not take Phenytoin until you are sure it is safe for you to do so.

Do not take Phenytoin

- if you are allergic (hypersensitive) to phenytoin, other hydantoin products or any of the other ingredients of Phenytoin capsules.

Take special care with Phenytoin

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.
- Porphyria (an inherited disease that affects haemoglobin biosynthesis).

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.

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 (HLA-B*1502), discuss this with your doctor before taking Phenytoin.

Taking other medicines

Some medicines can affect the way Phenytoin works, or Phenytoin itself can reduce the effectiveness of other medicines taken at the same time. These include:

- Medicines used for heart and circulation problems (dicoumarol, digitoxin, amiodarone, furosemide, quinidine, reserpine, warfarin, and calcium channel blockers e.g. diltiazem and nifedipine).
- Medicines used for epilepsy (carbamazepine, lamotrigine, phenobarbital, sodium valproate and valproic acid, succinimides e.g. ethosuximide and vigabatrin).
- Medicines used to treat fungal infections (e.g. amphotericin B, fluconazole, itraconazole, ketoconazole and miconazole).
- Medicines used for tuberculosis and other infections (chloramphenicol, isoniazid, rifampicin, sulfonamides, doxycycline, ciprofloxacin and nelfinavir).
- Medicines used for stomach ulcers (omeprazole, sucralfate, the medicines known as H2 antagonists e.g. cimetidine, ranitidine, famotidine and some antacids).
- Medicines used for asthma and bronchitis (theophylline).
- Medicines used for pain and inflammation (phenylbutazone, 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 and viloxazine).
- 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).
- Medicines used for cancer (antineoplastic agents).
- Muscle relaxants used for surgery (neuromuscular blockers), some anaesthetic drugs (halothane) and methadone.
- Some products available without a prescription (folic acid, theophylline, 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.

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

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.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Phenytoin.

Taking Phenytoin with food or drink

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 or breast-feeding

If you think you might be pregnant, or are planning to get pregnant, tell your doctor before you take Phenytoin.

You should not take phenytoin if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

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 operate tools or machinery or carry out other hazardous activities.

Important information about some of the ingredients of Phenytoin

Phenytoin contains lactose, a type of sugar. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE PHENYTOIN CAPSULES

Always take Phenytoin exactly as your doctor has told you. You should check with your doctor if you are not sure.

It is best to take Phenytoin at the same time each day.

Swallow the capsules whole, with plenty of water.

Adults

The amount of Phenytoin 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

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

The dose of Phenytoin for elderly patients who may be taking other medicines may also need careful consideration and adjustment by their doctor.

If you take more Phenytoin than you should

Phenytoin is dangerous in overdose. If you or someone else accidentally takes too much phenytoin contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any Phenytoin left or not, as this will allow easier identification of the medicine.

If you forget to take Phenytoin

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 missed dose.**

If you stop taking Phenytoin

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

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

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.

- 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, or toxic epidermal necrolysis (TEN). **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 decreases in the number of red cells, white cells or platelets. Your doctor may take regular blood samples to test for these effects.
- 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:

- **Effects on your nervous system:** 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.
- **Effects on your skin:** skin rash including measles-like reactions which are mild.
- **Effects on your stomach and intestines:** feeling sick, being sick and constipation.
- **Effects on your blood and lymph system:** swelling of the lymph glands.
- **Effects on your liver and kidney:** inflammation of the kidneys and liver, liver damage (seen as yellowing of the skin and whites of the eye).
- **Effects on your reproductive system and breasts:** changes in the shape of the penis, painful erection.
- **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 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.
- **Effects on medical tests:** increased levels of blood sugar, or decreased levels of blood calcium, 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 pain or fractures.
- 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.

If any of the side effects get serious or lasts longer than a few days, or if you notice other unwanted effects, tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort, Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PHENYTOIN CAPSULES

- Keep out of the reach and sight of children.
- Do not use Phenytoin after the expiry date, which is printed on the end of the carton and also on the bottle label. The expiry date refers to the last day of the 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
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Phenytoin Capsules contain

The name of this medicine is Phenytoin sodium NRI 100mg Capsules. The active substance in your capsules is phenytoin sodium. Each hard capsule contains 100mg of the active ingredient phenytoin sodium. Other ingredients include 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 NRI 100mg Capsules are hard gelatin capsules with an orange transparent coloured cap printed with “146” and white coloured body, containing white granular powder. Phenytoin sodium NRI 100mg Capsules are supplied in a HDPE capsule container with a child-resistant polypropylene cap. Each bottle contains 84 capsules.

Marketing Authorisation Holder

The Marketing Authorisation holder of these capsules is Lime Pharma Ltd., McKenzie House, Bury Street, Ruislip, Middlesex, HA4 7TL, UK

Manufacturer:

Actavis UK Limited, Whiddon Valley, Barnstaple, North Devon, EX32 8NS, UK.

This leaflet was prepared in 06/2016

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- 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.
- 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.

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5. HOW TO STORE PHENYTOIN CAPSULES

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6. FURTHER INFORMATION

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What Phenytoin Capsules look like and contents of the pack

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Marketing Authorisation Holder

The Marketing Authorisation holder of these capsules is Lime Pharma Ltd., McKenzie House, Bury Street, Ruislip, Middlesex, HA4 7TL, UK

Manufacturer:

Auden McKenzie (Pharma Division) Ltd, McKenzie House, Bury Street, Ruislip, Middlesex, HA4 7TL, United Kingdom.

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