

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Epanutin® 100mg Hard Capsules
(Phenytoin Sodium)

Your medicine is available by the above name, but will be referred to as Epanutin Hard Capsules throughout the remainder of the leaflet.

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

1. What Epanutin Hard Capsules are and what they are used for

Epanutin Hard Capsules are one of a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy.

Epanutin Hard 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. Epanutin Hard 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 Epanutin Hard Capsules.

2. What you need to know before you take Epanutin Hard Capsules

Do not take Epanutin Hard Capsules

- 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. hydantoins).

Warnings and precautions

Talk to your doctor or pharmacist before taking Epanutin Hard Capsules.

Medicines are not always suitable for everyone. Your doctor needs to know before you take Epanutin Hard Capsules 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).

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 the symptoms of the sudden, unexpected stopping of the heart (known as cardiac arrest). If you or someone you know is taking Epanutin and experiencing these symptoms, **seek immediate medical support.**

- slower heartbeat (known as bradycardia).

A small number of people being treated with antiepileptics such as Epanutin 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 Epanutin Hard 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 Epanutin Hard Capsules.

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

Other medicines and Epanutin Hard 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 Epanutin Hard Capsules work and Epanutin Hard 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, warfarin, calcium channel blockers e.g. diltiazem, mexiletine, nicardipine, 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)
- 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, sulphonamides, sulfadiazine, sulfamethoxazole-trimethoprim, doxycycline, ciprofloxacin, efavirenz, fosamprenavir, indinavir, lopinavir/ritonavir, ritonavir and saquinavir)
- Medicines used for stomach ulcers (omeprazole, sucralate, 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 (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)
- 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.

Epanutin Hard Capsules may also interfere with certain laboratory tests that you may be given.

Epanutin Hard Capsules with food, drink and alcohol

Epanutin Hard 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, contraception in women and breast-feeding

Pregnancy

If you are pregnant consult your doctor promptly. 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 the pregnancy. Your doctor may decide to change your treatment. Closer monitoring of your unborn child could also be considered.

Epanutin Hard Capsules may cause birth defects. If you take Epanutin Hard Capsules during pregnancy your baby has a higher risk of having a birth defect. Birth defects which have been reported include facial, skull, nail, finger and heart abnormalities.

If you are of childbearing age and plan to become pregnant, consult your doctor for a preconceptional visit. You should discuss your treatment options with your doctor.

If you take Epanutin Hard Capsules during pregnancy, your baby is also at risk for 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.

Contraception in women

If you are of childbearing age, you should discuss your treatment options and effective methods of birth control with your doctor. Epanutin Hard Capsules may result in a failure of hormonal contraceptives, hence you should be counselled regarding the use of other effective contraceptive methods.

Breast-feeding

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

Driving and using machines

Epanutin Hard Capsules 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.

Epanutin Hard Capsules contain lactose, a type of sugar.

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

3. How to take Epanutin Hard 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 Epanutin Hard Capsules at the same time each day.
Swallow the capsules whole, with plenty of water.

Adults

The amount of Epanutin Hard 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.

Use in 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 Epanutin Hard 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 Epanutin Hard Capsules than you should

Epanutin Hard Capsules are dangerous in overdose. If you accidentally take too much Epanutin Hard 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 Epanutin Hard Capsules left or not.

If you forget to take Epanutin Hard 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 Epanutin Hard Capsules

Do not stop taking Epanutin Hard 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 Epanutin Hard 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 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 and taste change.
- **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:** 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 medical tests:** increased levels of blood sugar, or decreased levels of blood calcium, 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.
- **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 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.

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 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.

5. How to store Epanutin Hard Capsules

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use Epanutin Hard Capsules after the expiry date which is stamped on the pack.

The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If your medicine becomes discoloured or shows any signs of deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information

What Epanutin Hard Capsules contain

Each hard capsules contains 100mg of the active ingredient, Phenytoin Sodium.

The other ingredients are lactose monohydrate, magnesium stearate, gelatin, titanium dioxide (E171), sodium lauryl sulfate, erythrosine (E127), quinoline yellow (E104) and ink (shellac glaze ~ 45% in ethanol, black iron oxide, N-butyl alcohol, purified water, propylene glycol, anhydrous ethanol, isopropyl alcohol, ammonium hydroxide 28%).

What Epanutin Hard Capsules look like and contents of the pack

Epanutin hard capsules are available as a white powder in a No3 hard gelatin capsule with a white opaque body and an orange cap radially printed in 'EPANUTIN 100'.

The capsules are packed in a plastic container which contains a desiccant. The desiccant should not be eaten.

They are available in a pack size of 100 capsules.

Manufacturer: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany.

Procured from within the EU and repackaged by: Amimed Direct Ltd, Hendon, London, NW9 6AQ.

Product Licence Holder: Sam Pharma Ltd, Unit 20 Garrick Industrial Estate, Irving Way, Hendon, London, NW9 6AQ.

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**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

**Phenytoin Sodium Flynn 100mg
Hard Capsules**

Your medicine is available by the above name, but will be referred to as Phenytoin Sodium Flynn Hard Capsules throughout the remainder of the leaflet.

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

1. What Phenytoin Sodium Flynn Hard Capsules are and what they are used for

Phenytoin Sodium Flynn Hard Capsules are one of a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy.

Phenytoin Sodium Flynn Hard 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 Sodium Flynn Hard 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 Sodium Flynn Hard Capsules.

2. What you need to know before you take Phenytoin Sodium Flynn Hard Capsules

Do not take Phenytoin Sodium Flynn Hard Capsules

- 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. hydantoins).

Warnings and precautions

Talk to your doctor or pharmacist before taking Phenytoin Sodium Flynn Hard Capsules.

Medicines are not always suitable for everyone. Your doctor needs to know before you take Phenytoin Sodium Flynn Hard Capsules 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).

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 the symptoms of the sudden, unexpected stopping of the heart (known as cardiac arrest). If you or someone you know is taking Phenytoin 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.

Serious skin side effects can rarely occur during treatment with Phenytoin Sodium Flynn Hard 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 Sodium Flynn Hard Capsules.

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

Other medicines and Phenytoin Sodium Flynn Hard 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 Sodium Flynn Hard Capsules work and Phenytoin Sodium Flynn Hard 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, warfarin, calcium channel blockers e.g. diltiazem, mexiletine, nicardipine, 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)
- 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, sulphonomides, sulfadiazine, sulfamethoxazole-trimethoprim, doxycycline, ciprofloxacin, efavirenz, fosamprenavir, indinavir, lopinavir/ritonavir, 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 (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 (ciclosporin 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)
- 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 Sodium Flynn Hard Capsules may also interfere with certain laboratory tests that you may be given.

Phenytoin Sodium Flynn Hard Capsules with food, drink and alcohol

Phenytoin Sodium Flynn Hard 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, contraception in women and breast-feeding

Pregnancy

If you are pregnant consult your doctor promptly. 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 the pregnancy. Your doctor may decide to change your treatment. Closer monitoring of your unborn child could also be considered.

Phenytoin Sodium Flynn Hard Capsules may cause birth defects. If you take Phenytoin Sodium Flynn Hard Capsule during pregnancy your baby has a higher risk of having a birth defect. Birth defects which have been reported include facial, skull, nail, finger and heart abnormalities.

If you are of childbearing age and plan to become pregnant, consult your doctor for a preconceptional visit. You should discuss your treatment options with your doctor.

If you take Phenytoin Sodium Flynn Hard Capsules during pregnancy, your baby is also at risk for 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.

Contraception in women

If you are of childbearing age, you should discuss your treatment options and effective methods of birth control with your doctor. Phenytoin Sodium Flynn Hard Capsules may result in a failure of hormonal contraceptives, hence you should be counselled regarding the use of other effective contraceptive methods.

Breast-feeding

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

Driving and using machines

Phenytoin Sodium Flynn Hard Capsules 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.

Phenytoin Sodium Flynn Hard Capsules contain lactose, a type of sugar.

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

3. How to take Phenytoin Sodium Flynn Hard 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 Sodium Flynn Hard Capsules at the same time each day. Swallow the capsules whole, with plenty of water.

Adults

The amount of Phenytoin Sodium Flynn Hard 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.

Use in 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 Sodium Flynn Hard 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 Sodium Flynn Hard Capsules than you should

Phenytoin Sodium Flynn Hard Capsules are dangerous in overdose. If you accidentally take too much Phenytoin Sodium Flynn Hard 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 Sodium Flynn Hard Capsules left or not.

If you forget to take Phenytoin Sodium Flynn Hard 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 Sodium Flynn Hard Capsules

Do not stop taking Phenytoin Sodium Flynn Hard 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 Sodium Flynn Hard 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 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 and taste change.
- **Effects on your skin:** skin rash including measles-like reactions which are mild.
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- **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:** 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 medical tests:** increased levels of blood sugar, or decreased levels of blood calcium, 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.
- **Effects on your respiratory system:** problems breathing, inflammation of the lining of the lung.
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- **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.

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5. How to store Phenytoin Sodium Flynn Hard Capsules

Keep out of the sight and reach of children.

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Do not use Phenytoin Sodium Flynn Hard Capsules after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If your medicine becomes discoloured or shows any signs of deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information

What Phenytoin Sodium Flynn Hard Capsules contain

Each hard capsules contains 100mg of the active ingredient, Phenytoin Sodium. The other ingredients are lactose monohydrate, magnesium stearate, gelatin, titanium dioxide (E171), sodium lauryl sulfate, erythrosine (E127), quinoline yellow (E104) and ink (shellac glaze ~ 45% in ethanol, black iron oxide, N-butyl alcohol, purified water, propylene glycol, anhydrous ethanol, isopropyl alcohol, ammonium hydroxide 28%).

What Phenytoin Sodium Flynn hard Capsules look like and contents of the pack

Phenytoin Sodium Flynn hard capsules are available as a white powder in a No3 hard gelatin capsule with a white opaque body and an orange cap radially printed in 'EPANUTIN 100'. The capsules are packed in a plastic container which contains a desiccant. The desiccant should not be eaten. They are available in a pack size of 100 capsules.

Manufacturer: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany.

Procured from within the EU and repackaged by: Amimed Direct Ltd, Hendon, London, NW9 6AQ.

Product Licence Holder: Sam Pharma Ltd, Unit 20 Garrick Industrial Estate, Irving Way, Hendon, London, NW9 6AQ.

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