APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Phlexy 250 mg/5 ml (Injection)

Every 5 ml contains phenytoin sodium 250 mg.

Read all of this leaflet carefully before you are given Phlexy 250 mg/5 ml

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **Phlexy 250 mg/5 ml** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT PHLEXY 250 mg/5 ml CONTAINS

Each 5 ml vial contains:

Phenytoin Sodium B.P..... 250 mg

Contains: Ethanol (96 %)..... % v/v

The other ingredients are: propylene glycol and sodium hydroxide in water for injection.

WHAT PHLEXY 250 mg/5 ml IS USED FOR

Phlexy 250 mg/5 ml is a solution for injection containing phenytoin. It belongs to a group of medicines called antiepileptic medicines.

Phlexy 250 mg/5 ml can be used to treat epileptic seizures or fits (status epilepticus). It can also be used to control or prevent seizures during or after brain surgery.

If you are unsure why **Phlexy 250 mg/5 ml** has been prescribed for you, you should consult your doctor.

BEFORE YOU ARE GIVEN PHLEXY 250 mg/5 ml

You should not be given Phlexy 250 mg/5 ml if:

- You are allergic (hypersensitive) to phenytoin or any of the other ingredients. (Refer to "WHAT **Phlexy 250 mg/5 ml** CONTAINS").
- You have porphyria.
- You suffer from certain conditions that affect the heart rhythm, for example a decreased heart rate (sinus bradycardia), heart block (sino-atrial block or A-V block) or Adams-Stoke syndrome.
- You are using any medication containing lidocaine.

Special care should be taken with Phlexy 250 mg/5 ml

- A small number of people being treated with anti-epileptics such as **Phlexy 250 mg/5 ml** 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 occur during treatment with **Phlexy 250 mg/5 ml**. If you have had such a reaction with previous treatment, discuss this with your doctor.

Inform your doctor if you have:

- Low blood pressure or heart failure.
- Tonic seizures.
- Heart rhythm problems.
- Liver disease
- Diabetes

Receiving Phlexy 250 mg/5 ml with food and drink

Drinking alcohol can affect the concentration of phenytoin in your blood.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby while receiving Phlexy 250 mg/5 ml, please consult your doctor, pharmacist or other health care professional for advice.

You should not receive **Phlexy 250 mg/5 ml** if you are pregnant or breastfeeding your baby.

Driving and using machinery:

Phlexy 250 mg/5 ml may make you feel dizzy or drowsy. If you experience any of these symptoms, do not drive or operate any tools or machinery.

Important information about some of the ingredients of Phlexy 250 mg/5 ml

Phlexy 250 mg/5 ml contains alcohol and may be harmful if you suffer from alcoholism. It should be taken into account in pregnant or breastfeeding women, children and high risk groups such as patients with liver disease.

Using other medicines with Phlexy 250 mg/5 ml:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The blood levels of Phlexy 250 mg/5 ml may be increased by the simultaneous intake of the following medicines:

- Alcohol (acute intake)
- Azapropazone, phenylbutazone, salicylates (used for pain and arthritis)
- Halothane (used in operations for anaesthesia)
- Tolbutamide (used to treat high blood sugar levels)

The blood levels of Phlexy 250 mg/5 ml may be decreased by the simultaneous intake of the following medicines:

- Alcohol (chronic intake)
- Rifampicin (used to treat tuberculosis)
- Ciprofloxacin (antibiotics used to treat infections)
- Vigabatrin (used to treat fits)
- Sucralfate (used for stomach ulcers)
- Theophylline (used for asthma and bronchitis)
- Reserpine (used to treat high bold pressure)
- Diazoxide (used to treat low blood sugar levels)

The blood levels of Phlexy 250 mg/5 ml may be increased or decreased by the simultaneous intake of the following medicines:

- Carbamazepine, phenobarbital, sodium valproate, valproic acid (used to treat fits)
- Antineoplastic agents (used in the management of cancer)
- Chlordiazepoxide, diazepam (used for sleeplessness and psychiatric disorders)

The blood levels and effects of the following medicines may be altered by the simultaneous intake of Phlexy 250 mg/5 ml:

- Doxycycline, praziquantel, tetracycline (antibiotics used to treat infections)
- Lamotrigine (used to treat fits)
- Azoles (used to treat fungal infections)
- Teniposide (used in the management of cancer)
- Theophylline (used for asthma and bronchitis)
- Digoxin, nicardipine, nimodipine, quinidine, verapamil (used to treat heart and circulation problems)
- Corticosteroids
- Warfarin (used to thin blood)
- Furosemide (water tablets)

- Oestrogens, oral contraceptives (hormone replacement therapy and oral contraceptives)
- Diazoxide (used to treat low blood sugar levels)
- Alcuronium, pancuronium, vecuronium (used in operations to relax muscles)
- Methadone (used for pain)
- Chlorpropamide, glyburide, tolbutamide (used to treat high blood sugar levels)
- Clozapine, paroxetine, sertraline (used for sleeplessness, depression and psychiatric disorders)
- Vitamin D

HOW PHLEXY 250 mg/5 ml WILL BE ADMINISTERED TO YOU:

You will not be expected to give yourself **Phlexy 250 mg/5 ml**. It will be given to you by a person qualified to do so. **Phlexy 250 mg/5 ml** will be given by injection into one of your large veins (intravenously). For single use only.

If you receive more Phlexy 250mg/5 ml injection than you should:

Since a healthcare professional will administer **Phlexy 250 mg/5 ml**, he/she will control the dosage. However, in the event of an overdosage your doctor will take the necessary corrective action.

Effects when treatment with Phlexy 250 mg/5 ml is stopped:

Abrupt discontinuation of **Phlexy 250 mg/5 ml** treatment in patients susceptible to fits may cause an increase in the frequency of fits including status epilepticus.

POSSIBLE SIDE EFFECTS

Phlexy 250 mg/5 ml can have side effects.

Not all side effects reported for **Phlexy 250 mg/5 ml** are included in this leaflet. Should your general health worsen while receiving **Phlexy 250 mg/5 ml**, please consult your doctor, pharmacist or other healthcare professional for advice.

*If any of the following happens, stop **Phlexy 250 mg/5 ml** and tell your doctor immediately or go to*

the casualty department at your nearest hospital.

- If you experience irritation at the site where **Phlexy 250 mg/5 ml** is injected. This may be minor, but can be serious.
- If you develop a severe skin rash that causes blistering (this can 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 blood 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 the 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, incorrect perception of motion, sleeplessness or excessive sleepiness, nervousness, twitching muscles, headaches, taste disturbances, fits.
- skin rash including measles-like reactions which are mild.
- nausea, vomiting and constipation.
- swelling of the lymph glands.
- inflammation of the kidneys and liver, liver damage.

- changes in the hands with difficulty in straightening the fingers, changes in facial features, enlarged lips or gums, increased or abnormal body hair.
- decreased levels of blood sugar, 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.
- problems breathing, inflammation of the lining of the lung.
- problems with the body's defense against infection, inflammation of the wall of the arteries.
- low blood pressure, enlargement of blood vessels. Your blood pressure may also be lowered and experience heart problems when **Phlexy 250 mg/5 ml** is injected into your vein too quickly.

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.

STORING AND DISPOSING OF PHLEXY 250 mg/5 ml

- Store at or below 25 ºC.
- Keep the vials in the carton until required for use.
- Protect from light.
- The injection cannot be added to other medicines due to the possible precipitation of phenytoin acid.
- If only a part of the vial is used, throw away the remaining solution.
- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date printed on the label or carton.
- Do not store this medicine in a damp place such as a bathroom medicine cabinet or near the kitchen sink.
- Store in the original strip or container.
- Keep the container tightly closed.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

PRESENTATION OF PHLEXY 250 mg/5 ml

Phlexy 250 mg/5 ml is available in a 5 ml Ph. Eur. type I clear transparent flint glass vial with a dark grey bromobutyl rubber stopper and a dark blue aluminium flip off seal. Vials are supplied in cartons of 5,10 or 20.

IDENTIFICATION OF PHLEXY 250 mg/5 ml

Clear colourless solution free from any particulate matter.

REGISTRATION NUMBER

45/2.5/0493

NAME AND ADDRESS OF REGISTRATION HOLDER

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DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET.

5 June 2014