PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

EPANUTIN® READY MIXED PARENTERAL (Injection)

Phenytoin sodium

Read this leaflet carefully before you are given EPANUTIN READY MIXED PARENTERAL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- EPANUTIN READY MIXED PARENTERAL 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.

1. WHAT EPANUTIN READY MIXED PARENTERAL CONTAINS:

The active ingredient of EPANUTIN READY MIXED PARENTERAL is phenytoin sodium. EPANUTIN READY MIXED PARENTERAL contains the following inactive ingredients: alcohol, propylene glycol, sodium hydroxide, water for injection.

2. WHAT EPANUTIN READY MIXED PARENTERAL IS USED FOR:

EPANUTIN READY MIXED PARENTERAL belongs to a group of medicines known as anti-epileptic medicines. EPANUTIN READY MIXED PARENTERAL can be used to prevent and treat seizures when the oral route is not suitable.

3. BEFORE YOU ARE ADMINISTERED EPANUTIN READY MIXED PARENTERAL:

You may have been given EPANUTIN READY MIXED PARENTERAL as a single dose to control *status epilepticus*. In this case, you will only be able to read this leaflet after you have had the product given to you. The questions below will have been considered by your doctor before you were given EPANUTIN READY MIXED PARENTERAL, but the urgent need for treatment may have been more

important than some of the normal cautions. Check them now, especially if you are going to continue to be given EPANUTIN READY MIXED PARENTERAL (or any other form of the active ingredient, phenytoin).

- Are you pregnant, trying to become pregnant, or breastfeeding?
- Have you ever had a reaction (allergic) to phenytoin, phenytoin sodium, EPANUTIN READY MIXED PARENTERAL or any of its ingredients, or any other EPANUTIN preparation?
- Are you taking any other medicines? There is a list of medicines that EPANUTIN READY MIXED PARENTERAL interacts with in the next section.
- Do you have a heart condition? (EPANUTIN READY MIXED PARENTERAL can be used to treat some cardiac dysrhythmias)
- Do you drink large amounts of alcohol?
- Do you suffer from liver disease?
- Do you have porphyria (an inherited disease that affects haemoglobin biosynthesis)? Your doctor will tell you if you suffer from this.
- Do you have a family history of Anticonvulsant Hypersensitivity Syndrome (AHS), or have you been diagnosed with AHS?
- Do you have thoughts of harming or killing yourself? If at any time you have had these thoughts, immediately contact your doctor.
- Have you ever experienced a serious hypersensitivity reaction which includes skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal organs when you have previously been exposed to certain medicines such as EPANUTIN READY MIXED PARENTERAL? This reaction is called drug rash with eosinophilia symptoms (DRESS). If you have experienced any of these symptoms, tell your doctor immediately.
- Have you experienced irritation, inflammation, tenderness, dying or sloughing of skin cells at the site where EPANUTIN READY MIXED PARENTERAL was injected, or have you experienced discolouration, pain or swelling of the skin away from the site of injection? These symptoms may be minor but can also be serious. These may be signs of a condition known as Purple Glove Syndrome.

Giving other medicines with EPANUTIN READY MIXED PARENTERAL:

EPANUTIN READY MIXED PARENTERAL sometimes affects the action of other medicines and

sometimes EPANUTIN READY MIXED PARENTERAL is affected by other medicines. Always tell your pharmacist you are taking EPANUTIN when you buy medicines. If you require an operation or will visit your dentist or doctor, let them know that you are taking EPANUTIN.

EPANUTIN READY MIXED PARENTERAL may interact with other medicines use to treat:

- Epilepsy (carbamazepine, lamotrigine, phenobarbitone, sodium valproate, valproic acid, succinimides like ethosuximide and vigabatrin)
- Fungal infections (e.g. amphotericin B, fluconazole, itraconazole, ketoconazole and miconazole)
- Tuberculosis and other infections (chloramphenicol, isoniazid, rifampicin, sulphonamides, ciprofloxacin and doxycycline)
- Asthma and bronchitis (theophylline)
- Pain and inflammation (phenylbutazone, salicylates and steroids)
- Stomach ulcers (omeprazole, sucralfate, the medicines known as H_2 antagonists e.g. cimetidine, ranitidine and some antacids)
- Sleeplessness, depression and psychiatric disorders (chlordiazepoxide, clozapine, diazepam, disulfiram, methylphenidate, paroxetine, phenothiazines, trazodone, tricyclic antidepressants, sertraline and viloxazine)
- Cancer (antineoplastic agents) (fluorouracil and teniposide)
- Heart and circulation problems (dicumarol, amiodarone, reserpine, digoxin, furosemide, quinidine, warfarin and calcium channel blockers e.g. nifedipine, verapamil)
- Diabetes (tolbutamide)
- Antiretrovirals or HIV infection treatment (zidovudine or nelfinavir)
- Some hormone replacement therapies (oestrogens), oral contraceptives (birth control pills)
- Halogenated inhalation products
- Some products available without prescription (folic acid, antacids, theophylline, vitamin D, salicylates like aspirin)
- EPANUTIN READY MIXED PARENTERAL may also interfere with certain laboratory tests that you may be given
- Excessive alcohol intake can affect the concentration of phenytoin, the active ingredient of EPANUTIN READY MIXED PARENTERAL, in your blood.

Pregnancy and breastfeeding:

Pregnancy:

EPANUTIN READY MIXED PARENTERAL should be avoided if you are pregnant or think you may be unless your doctor considers EPANUTIN READY MIXED PARENTERAL to be essential for you.

Breastfeeding:

EPANUTIN READY MIXED PARENTERAL must not be taken during breastfeeding.

Ask your doctor or pharmacist for advice before taking EPANUTIN READY MIXED PARENTERAL.

Driving and using machinery:

Be advised not to drive a car or operate potentially dangerous machinery until it is known that EPANUTIN READY MIXED PARENTERAL does not affect your ability to engage in these activities.

4. HOW TO RECEIVE EPANUTIN READY MIXED PARENTERAL:

You will be in hospital when you are given EPANUTIN READY MIXED PARENTERAL.

Use in *status epilepticus*:

Adults:

The amount of EPANUTIN READY MIXED PARENTERAL needed varies from person to person. Most people need between 300 mg – 400 mg a day, taken in three or four equally divided doses. Occasionally higher doses, up to 600 mg daily are needed.

Children:

Children usually start on a dose that depends on their weight (10 to 20 mg/kg body mass) and is given as 1 to 3 mg/kg/minute. For infants, the dosage may also be calculated on the basis of 250 mg/m^2 body surface. The appropriate maintenance dosing (oral if possible) should be administered in divided doses; the recommended daily maintenance dosage is usually in the range of 4 to 8 mg/kg.

Use in neurosurgery:

Injections of EPANUTIN READY MIXED PARENTERAL may be given as for “Use in *status epilepticus*” mentioned above.

Use in cardiac dysrhythmias:

An intravenous injection is given at a dose based on body weight (usually 3,5 to 5mg per kg of body weight). This may be repeated a second time.

5. POSSIBLE SIDE EFFECTS:

Side effects have been reported with the use of EPANUTIN READY MIXED PARENTERAL.

Not all side effects reported for EPANUTIN READY MIXED PARENTERAL are included in this leaflet. Should your general health worsen while taking EPANUTIN READY MIXED PARENTERAL, please consult your doctor, pharmacist or other healthcare professional for advice.

These might be:

- Effects on the *central nervous system* (brain). These include unusual eye movements, unsteadiness, difficulty in controlling movements, shaking, abnormal or uncoordinated movements, slurred speech, confusion, pins and needles or numbness, drowsiness, dizziness or vertigo, sleeplessness, nervousness, twitching muscles, headaches, loss of feeling in the hands and feet.
- *Skin rash or itchiness*. Many types of skin rash have been reported with the use of EPANUTIN READY MIXED PARENTERAL. Some are minor (e.g. measles-like or mild dermatitis). Others, although rare, are more serious such as Stevens-Johnson Syndrome or toxic epidermal necrolysis (TEN), which cause blistering and can affect the mouth and tongue. Rash may also be a first sign of other side-effects of EPANUTIN. If you get a rash, your doctor may advise you to stop taking EPANUTIN READY MIXED PARENTERAL until it clears up. If the rash recurs, does not clear up or a serious reaction is suspected, your doctor may advise you not to take EPANUTIN again.
- *Hypersensitivity reaction or syndrome* – Fever, skin rash, swollen glands may occur, usually within the first two months of treatment. Changes in liver function, increased numbers of white blood cells and joint pains may occur as part of this syndrome. Inflammation in various parts of your body including the joints, skin, kidneys, a condition known as systemic lupus erythematosus, may occur on rare occasions.
- Symptoms of a serious hypersensitivity reaction called DRESS include skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal organs.
- *Swelling of the lymph glands* (a part of your body's natural defence system) and other disorders of the lymph glands may occur. This may be accompanied by fever or rash and may affect your liver but may also be a sign of a problem with your lymph glands.
- *Abnormalities of the blood* including decreases in the number of red cells, white cells or platelets

(parts of the blood which help it clot). The first signs you might notice could be bruising, fever, pallor or sore throat. Your doctor may take regular blood samples to test for this.

- *Injection site irritation:* You may experience irritation, inflammation, tenderness, dying or sloughing of skin cells at the site where EPANUTIN READY MIXED PARENTERAL was injected. Discolouration, pain or swelling of the skin away from the site of injection may also occur. These symptoms may be minor but can also be serious and are signs of a condition known as Purple Glove Syndrome.
- Hepatitis (inflammation of the liver) or liver damage which may be recognised by yellowing of the skin and whites of the eyes and changes in liver function.
- Nausea, vomiting, constipation
- Inflammation of the kidneys
- Other side effects have included: 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, changes in the shape of the penis and painful erection, a condition affecting the joints known as polyarthropathy.
- EPANUTIN READY MIXED PARENTERAL may alter the amount of vitamin D in your body. 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.

6. STORING AND DISPOSING OF EPANUTIN READY MIXED PARENTERAL:

The storage of EPANUTIN READY MIXED PARENTERAL will not be your responsibility. However, it should be stored at room temperature (below 25 °C) and protected from light and excessive heat.

7. PRESENTATION OF EPANUTIN READY MIXED PARENTERAL:

EPANUTIN READY MIXED PARENTERAL is available in a vial.

8. IDENTIFICATION OF EPANUTIN READY MIXED PARENTERAL:

A clear, colourless ready mixed solution containing 50 mg phenytoin sodium per ml in a glass vial.

9. REFERENCE NUMBER:

B1624 (Act 101/1965)

10. NAME AND ADDRESS OF THE APPLICANT:

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