

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

EPANUTIN® FORTE SUSPENSION

Phenytoin

Read this leaflet carefully before you start to take EPANUTIN FORTE

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

The active ingredient of EPANUTIN FORTE is phenytoin. EPANUTIN FORTE contains the following inactive ingredients: magnesium aluminium silicate, sodium benzoate, sodium carboxymethyl cellulose, glycerine, polysorbate 40, sucrose, alcohol (each 5 ml dose contains 0,48 % of alcohol), vanillin, banana flavour, orange oil, citric acid, yellow colourant and water.

2. WHAT EPANUTIN FORTE IS USED FOR:

EPANUTIN FORTE belongs to a group of medicines known as anti-epileptic medicines. EPANUTIN FORTE can be used to control your epilepsy. It can also be used to control or prevent seizures during or after brain surgery or severe head injury.

3. BEFORE YOU TAKE EPANUTIN FORTE:

If the answer to any of the following questions is “yes”, you should talk to your doctor or pharmacist before taking EPANUTIN FORTE as it may not be suitable for you.

- Are you pregnant, trying to become pregnant, or breastfeeding?

- Have you ever had a reaction (allergic) to phenytoin, phenytoin sodium, EPANUTIN FORTE or any of its ingredients, or any other EPANUTIN preparation?
- Are you taking any other medicines? There is a list of medicines that EPANUTIN FORTE interacts with in the next section.
- 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 FORTE? This reaction is called drug rash with eosinophilia symptoms (DRESS). If you have experienced any of these symptoms, tell your doctor immediately.

Taking other medicines with EPANUTIN FORTE:

EPANUTIN FORTE sometimes affects the action of other medicines and sometimes EPANUTIN FORTE 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 FORTE may interact with other medicines use to treat:

- Epilepsy (carbamazepine, lamotrigine, phenobarbital, 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 H₂ antagonists e.g. cimetidine, ranitidine and some antacids)
- Sleeplessness, depression and psychiatric disorders (chlordiazepoxide, clozapine, diazepam, disulfiram, methylphenidate, paroxetine, phenothiazines, trazodone, tricyclic antidepressants and viloxazine)
- Cancer (antineoplastic agents) (fluorouracil and teniposide)
- Heart and circulation problems (dicumarol, amiodarone, reserpine, digitoxin, 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), the anaesthetic agent halothane and some products available without prescription (folic acid, antacids, theophylline, vitamin D, salicylates like aspirin)
- EPANUTIN FORTE 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 FORTE, in your blood.

Pregnancy and Breastfeeding:

Pregnancy:

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

Breastfeeding:

EPANUTIN FORTE must not be taken during breastfeeding.

Ask your doctor or pharmacist for advice before taking EPANUTIN FORTE.

Driving and using machinery:

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

4. HOW TO TAKE EPANUTIN FORTE:

Always take EPANUTIN FORTE exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure. EPANUTIN FORTE is to be taken by mouth. **Shake well before use.**

Adults:

The amount of EPANUTIN FORTE 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:

Infants and children usually start on a dose that depends on their weight (5 mg per day for every kg they weigh) and is given as a divided dose (2 or 3 divided doses a day). The dose is then adjusted up to a maximum of 300 mg a day.

Keep taking EPANUTIN FORTE for as long as your doctor instructed you. Do not alter the dose yourself without your doctor's advice. Do not stop taking the EPANUTIN FORTE unless told to do so by your doctor. If you suddenly stop taking EPANUTIN FORTE, you may have a seizure. Should you need to stop taking EPANUTIN FORTE your doctor will decide which is the best method for you.

If you take more EPANUTIN FORTE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you take more EPANUTIN FORTE than you should, call your doctor immediately. If you cannot call your doctor, go to the nearest hospital or poison control centre at once. Always take the labelled medicine package with you, whether there is any EPANUTIN FORTE left or not. Some symptoms of overdosage include nausea, vomiting, slurred speech, tiredness.

If you forget to take EPANUTIN FORTE:

If you forget to take a dose, take it as soon as you remember unless it is time for the next dose. **Do not take two doses at the same time.** If you forget to take your medicine for more than one week, call your doctor before taking any more EPANUTIN FORTE.

Do not share EPANUTIN FORTE prescribed for you with others.

5. POSSIBLE SIDE EFFECTS

Side effects are reported with the use of EPANUTIN FORTE.

Not all side effects reported for EPANUTIN FORTE are included in this leaflet. Should your general health worsen while taking EPANUTIN FORTE, 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 (dizziness in high places), sleeplessness, nervousness, twitching muscles, headaches, loss of feeling in the hands and feet.
- *Skin rash or itchiness*. Many sorts of skin rash have been reported with the use of EPANUTIN FORTE. 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 FORTE 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 or 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.

- 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.
- Rare 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.
- Increased levels of blood sugar, or decreased levels of blood calcium or folic acid.
- EPANUTIN FORTE 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 FORTE:

Store all medicines out of reach of children. Store in a cool (below 25 °C), dry place.

This medicine is for you. Only a doctor can prescribe it for you. Do not share it with anyone else. It may harm them, even if they have the same symptoms as you.

DO NOT use EPANUTIN FORTE after the expiry date which is printed on the label. Return all unused medicine to your pharmacist. DO NOT dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF EPANUTIN FORTE:

Round amber glass or polyethylene terephthalate (PET) bottles of 237 ml with a white polypropylene closure.

8. IDENTIFICATION OF EPANUTIN FORTE:

EPANUTIN FORTE – a pleasant orange/banana flavoured, orange coloured suspension.

9. REFERENCE NUMBER:

B555 (Act 101/1965)

10. NAME AND ADDRESS OF THE APPLICANT:

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