

SCHEDULING STATUS: **S3**

EPANUTIN® READY MIXED PARENTERAL Injection

Phenytoin sodium 250 mg/5 mL

Sugar free

Read all of 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, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What EPANUTIN READY MIXED PARENTERAL is and what it is used for
2. What you need to know before you are given EPANUTIN READY MIXED PARENTERAL
3. How to receive EPANUTIN READY MIXED PARENTERAL
4. Possible side effects
5. How to store EPANUTIN READY MIXED PARENTERAL
6. Contents of the pack and other information

1. What EPANUTIN READY MIXED PARENTERAL is and what it 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. It is used to:

- Prevent and treat seizures during or after brain surgery
- Control severe epileptic seizures or fits (*status epilepticus*)

2. What you need to know before you are given EPANUTIN READY MIXED PARENTERAL

EPANUTIN READY MIXED PARENTERAL should not be administered to you

- If you are hypersensitive (allergic) to phenytoin or any of the other ingredients of EPANUTIN READY

MIXED PARENTERAL (listed in section 6), or other hydantoin medicines.

- If you have porphyria (an inherited disease that affects haemoglobin biosynthesis).
- If you suffer from certain conditions that affect the heart rhythm, for example a decreased heart rate (sinus bradycardia), heart block (sinoatrial block or A-V block) or Stokes-Adams syndrome.
- If you are also taking medicines used for HIV infection.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you are alcohol dependant.
- There is a risk of harm to the unborn child if EPANUTIN READY MIXED PARENTERAL is used during pregnancy. Women of childbearing age should use effective contraception during treatment with EPANUTIN READY MIXED PARENTERAL (see Pregnancy and breastfeeding).
- Black patients may be at greater risk of liver problems, serious skin reactions and allergic reactions.
- Some patients being treated with EPANUTIN READY MIXED PARENTERAL have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- If you have experienced irritation, inflammation, tenderness, dying or sloughing of skin cells at the site where EPANUTIN READY MIXED PARENTERAL was injected, or you have 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.
- If you have 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.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of EPANUTIN READY MIXED PARENTERAL, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms.

The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is within the first weeks of treatment. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of EPANUTIN READY MIXED PARENTERAL, you must not be re-started on EPANUTIN READY MIXED PARENTERAL at any time. If you develop a rash or these skin symptoms, stop receiving EPANUTIN READY MIXED PARENTERAL, seek urgent advice from a doctor and tell him that you are taking this medicine.

- If you are of Asian ancestry and tests have shown that you carry the genetic variant HLA-B*1502.
- If you suffer from liver disease.

Other medicines and EPANUTIN READY MIXED PARENTERAL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

EPANUTIN READY MIXED PARENTERAL sometimes affects the action of other medicines and sometimes EPANUTIN READY MIXED PARENTERAL is affected by other medicines.

EPANUTIN READY MIXED PARENTERAL may interact with other medicines. These include:

- Excessive alcohol intake can affect the concentration of phenytoin, the active ingredient of EPANUTIN READY MIXED PARENTERAL, in your blood.
- Pain and inflammation: salicylates and corticosteroids.
- Anaesthetic medicines: halogenated anaesthetics.
- Muscular relaxants used for surgery (neuromuscular blockers): alcuronium, cisatracurium, pancuronium, rocuronium, vecuronium.
- Antibacterial medicines: chloramphenicol, erythromycin, isoniazid, sulphonamides including co-trimoxazole, rifampicin, ciprofloxacin, doxycycline, tetracycline.
- Medicines used for epilepsy: felbamate, oxcarbazepine, sodium valproate, succinimides, topiramate, vigabatrin, carbamazepine, phenobarbital, valproic acid, lamotrigine.
- Medicines used for fungal infections: amphotericin B, fluconazole, itraconazole, ketoconazole, miconazole, voriconazole, azoles, posaconazole.
- Medicines used for cancer (antineoplastic medicines): capecitabine, fluorouracil, bleomycin, carboplatin, cisplatin, doxorubicin, methotrexate, teniposide.
- Medicines used to expel parasitic worms from the body (anthelmintics): albendazole, praziquantel.

- Medicines used for stomach ulcers: omeprazole, cimetidine and some antacids.
- Antiretrovirals used for HIV infection treatment: fosamprenavir, nelfinavir, ritonavir, zidovudine, delavirdine, efavirenz, indinavir, lopinavir/ritonavir, saquinavir.
- Medicines used for sleeplessness, depression and psychiatric disorders: chlorthalidone, diazepam, disulfiram, methylphenidate, trazodone, viloxazine, phenothiazines, clozapine, paroxetine, quetiapine, sertraline, tricyclic antidepressants, fluoxetine, fluvoxamine.
- Medicines used for asthma and bronchitis: theophylline.
- Medicines used for heart and circulation problems: amiodarone, diltiazem, nifedipine, ticlopidine, reserpine, digoxin, mexiletine, nicardipine, nimodipine, nisoldipine, quinidine, warfarin, verapamil.
- Medicines used to lower high blood cholesterol and triglycerides: fluvastatin, atorvastatin, simvastatin.
- Medicines used for organ and tissue transplants, to prevent rejection: tacrolimus, ciclosporin.
- Medicines used for diabetes: tolbutamide, chlorpropamide, glyburide and diazoxide.
- Some hormone replacement therapies (estrogens), oral contraceptives (birth control pills) and some products available without prescription (folic acid, antacids, theophylline, vitamin D, salicylates like aspirin and St John's Wort).
- Corticosteroids.
- Diuretics: furosemide.
- Oral blood thinners such as rivaroxaban, dabigatran, apixaban and edoxaban may have their effects reduced when used together with EPANUTIN READY MIXED PARENTERAL.
- EPANUTIN READY MIXED PARENTERAL may also interfere with certain laboratory tests.

EPANUTIN READY MIXED PARENTERAL with alcohol

Drinking alcohol can affect the concentration of phenytoin in your blood. Talk to your doctor or pharmacist for advice.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving EPANUTIN READY MIXED PARENTERAL.

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.

EPANUTIN READY MIXED PARENTERAL must not be taken during breastfeeding.

If you are a woman of childbearing age and are not planning a pregnancy, you should use effective contraception during treatment with EPANUTIN READY MIXED PARENTERAL. EPANUTIN READY MIXED PARENTERAL may affect how hormonal contraceptives, such as the contraceptive (birth control) pill, work and make them less effective at preventing pregnancy. Talk to your health care provider, who will discuss with you the most suitable type of contraception to use while you are taking EPANUTIN READY MIXED PARENTERAL.

If you are a woman of childbearing age and are planning a pregnancy, talk to your health care provider before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to EPANUTIN READY MIXED PARENTERAL.

If you are or think you might be pregnant, tell your health care provider straight away. You should not stop taking your medicine until you have discussed this with your health care provider. Stopping your medicine without consulting your health care provider could cause seizures which could be dangerous to you and your unborn child. Your health care provider may decide to change your treatment. Closer monitoring of your unborn child is also recommended.

Driving and using machines

It is not always possible to predict to what extent EPANUTIN READY MIXED PARENTERAL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EPANUTIN READY MIXED PARENTERAL affects them.

Do not 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.

EPANUTIN READY MIXED PARENTERAL contains alcohol (ethanol 96 %), propylene glycol and sodium

Alcohol (ethanol 96 %)

This medicine contains 446,7 mg of alcohol (ethanol 96 %) in each 5 mL solution.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its

effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are pregnant or breastfeeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

Propylene glycol

This medicine also contains 2,075 g propylene glycol in each 5 mL solution of phenytoin.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they are being given other medicines that contain propylene glycol or alcohol.

If you are pregnant or breastfeeding, do not take this medicine unless recommended by your doctor.

Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from liver or kidney disease, do not take this medicine unless recommended by your doctor.

Your doctor may carry out extra checks if you need to receive EPANUTIN READY MIXED PARENTERAL for more than 24 hours.

Propylene glycol in this medicine can have the same effects as drinking alcohol and increase the likelihood of side effects.

Use this medicine only if recommended by a doctor. Your doctor may carry out extra checks while you are taking this medicine.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per 5 mL solution, this is to say essentially 'sodium-free'.

3. How to receive EPANUTIN READY MIXED PARENTERAL

You will not be expected to give yourself EPANUTIN READY MIXED PARENTERAL. It will be given to you by a person who is qualified to do so.

Use in status epilepticus

The dose that is appropriate for you will be determined by your doctor.

If you receive more EPANUTIN READY MIXED PARENTERAL than you should

Since a health care provider will administer EPANUTIN READY MIXED PARENTERAL, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

The initial symptoms of overdosage are involuntary eye movement, the loss of full control of bodily movements, and difficulty with speaking. Other symptoms of overdosage include tremor, overactive or overresponsive reflexes, tiredness, drowsiness, slurred speech, blurred vision, nausea and vomiting.

If you forget to receive EPANUTIN READY MIXED PARENTERAL

Since a health care provider will administer EPANUTIN READY MIXED PARENTERAL, it is unlikely that the dose will be missed.

If you stop receiving EPANUTIN READY MIXED PARENTERAL

Treatment with EPANUTIN READY MIXED PARENTERAL should not be stopped abruptly because of the possibility of increased seizure frequency. If the doctor decides to reduce the dose, stop treatment or change your medication, this should be done gradually. However, in the event of an allergic or hypersensitivity reaction, rapid substitution of alternative therapy may be necessary.

4. Possible side effects

EPANUTIN READY MIXED PARENTERAL can have side effects.

Not all side effects reported for EPANUTIN READY MIXED PARENTERAL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving EPANUTIN READY MIXED PARENTERAL, please consult your health care provider for advice.

If any of the following happens, stop receiving EPANUTIN READY MIXED PARENTERAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to EPANUTIN READY MIXED PARENTERAL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any

of the following:

- Chest pain and difficulty breathing.
- Central nervous system depression.
- Many sorts of skin rash, sometimes accompanied by fever, may occur with the use of EPANUTIN READY MIXED PARENTERAL. Some are minor (e.g. measles-like or mild dermatitis). Rash may also be a first sign of other side effects of EPANUTIN READY MIXED PARENTERAL. 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.
- Liver failure, 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Dizziness or vertigo, unusual eye movements, pins and needles.
- Confusion, sleeplessness, nervousness.
- Unsteadiness or difficulty in controlling movements, slurred speech, abnormal or uncoordinated movements, headaches.
- Vertigo (dizziness).
- Low blood pressure.
- Nausea, vomiting.
- Muscle twitching.
- Local irritation, inflammation, tenderness or shedding of dead skin cells. 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.

Less frequent side effects

- 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.

- 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.
- Abnormality or difficulty with muscle movement, including jerky involuntary movements, muscular spasm and abnormal posture, shaking, numbness, loss of feeling in the hands and feet. Things may also taste different.
- Constipation, enlargement of the gums and lips.
- Abnormal body or facial hair.
- Changes in facial features, swelling of your gums and/or lips, inflammation in various parts of your body including the joints, skin, kidneys, a condition known as systemic lupus erythematosus, may occur.
- Changes in the shape of the penis and painful erection (Peyronie's disease).
- Antibody abnormalities.

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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, ~~or~~ pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform ([who-umc.org](https://www.who-umc.org)) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of EPANUTIN READY MIXED PARENTERAL.

5. How to store EPANUTIN READY MIXED PARENTERAL

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

6. Contents of the pack and other information

What EPANUTIN READY MIXED PARENTERAL contains

- The active substance is phenytoin sodium 250 mg per 5 mL.
- The other ingredients are 446,7 mg alcohol (ethanol 96 %), 2,075 g propylene glycol, 20,95 mg sodium (as sodium hydroxide) per 5 mL, and water for injection.

What EPANUTIN READY MIXED PARENTERAL looks like and contents of the pack

A clear, colourless ready mixed solution containing 50 mg phenytoin sodium per mL in a 6 mL flint glass vial.

EPANUTIN READY MIXED PARENTERAL is available in a 6 mL vial containing 250 mg (50 mg/mL) phenytoin sodium B.P.

Holder of Certificate of Registration

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