Sodium.

CONTRAINDICATIONS

Phenytoin is contraindicated in these patients with a history of hypersensitivity to phenytoin, its

CONTRADICTIONS

Phenytoin is contraindicated in these patients with a history of hypersensitivity to phenytoin, its

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Drug Enteral Feeding/Nutritional Preparations Interaction: Intragastric administration of antacids, oral contraceptives, and other drugs used to control gastric acid secretion, which may cause a high gastric pH, should be avoided since the pharmacokinetics of phenytoin are 
affected by the gastric pH. If phenytoin is required to be administered in this setting, the phenytoin dose should be adjusted to meet individual requirements. In most adults, the satisfactory maintenance dosage will be one capsule every three hours to four times a day. An increase to two or three capsules three times a day may be made, if necessary.

One-dose regimen: In adults, if seizure control is maintained with divided doses of three, 100 mg pills every 12 hours, a single daily dose of 300 mg may be used instead of three divided doses of 100 mg with a single daily dose of the quantity required, peak plasma levels may be lower than those achieved with the one-dose regimen. When converting from a one-dose regimen to a divided one for the first time, most patients require a one-day adjustment for peak plasma levels. If a one-dose regimen is used only for patients requiring 300 mg of drug daily. A major problem in maintaining uncomplicated patients may also be lessened when the patient reaches steady state with this drug once a day. However, patients should be cautioned not to miss a dose, inadvertently.

Only extended release phenytoin capsules, USP are recommended for once-a-day dosing for different diseases and conditions which cause phenytoin to remain in the blood, or plasma levels, to be therapeutic. Intravenous administration should not be given intramuscularly. Intramuscular administration should be used only for patients requiring 300 mg of drug daily. A major problem in maintaining uncomplicated patients may also be lessened when the patient reaches steady state with this drug once a day. However, patients should be cautioned not to miss a dose, inadvertently.

ADVERSE REACTIONS
Body as a Whole: Allergic reactions in the form of rash and rarely more serious forms (see Skin and Appendages paragraph below) and DRESS (see WARNINGS) have been observed. Anaphylaxis has also been reported. There have also been reports of worsening of pre-existing skin lesions, systemic lupus erythematosus, redness, and urticaria/skin rash.
Nervous System: The most common adverse reaction encountered with phenytoin therapy therapy are skeletal muscle reactions and also less common. Reactive episodes include epigastric, sublingual, speech, decreased coordination, somnolence, and mental confusion. Dizziness, vertigo, dizziness, tremor, transverse myelitis, retinal hemorrhages, and headaches have also been observed. There have also been rare reports of phenytoin-induced aplastic anemia, including thrombocytopenia, neutropenia, and anemia. Phenytoin has also been associated with drug fever, however, the clinical significance of this condition is unknown. It has been observed in patients receiving long-term phenytoin therapy. Drug fever is not completely bound to plasma proteins. Total exchange transfusion has been used in the treatment of severe intoxication in pediatric patients.

Treatment is nonspecific since there is no known antidote.

Drug Interaction: Drug interactions are often difficult to assess since the clinical relevance of the interaction is not always clear. Previous recommendations for the dosage adjustment of phenytoin due to different disease processes or dosage forms must be reevaluated. Currently monitoring of phenytoin serum levels should not be required.

Leading studies: Some patients may have an oral loading dose of phenytoin in adults who require rapid steady-state serum levels and where intravenous administration is not desirable. The dosage regimen should be based on a patient’s history and level of seizure control. Normal maintenance dosage is then instituted 24 hours after the loading dose, with frequent serum level determinations.

Dosing in Special Populations
Pediatric:With Acute and Newborn Patients: Due to an increased fraction of unbound phenytoin in patients with renal or hepatic disease, and with those with hypoproteinemia, the interpretation of total phenytoin plasma concentrations should be adjusted to these patient populations. Untoward phenytoin concentrations may be more evident in these pediatric patient populations. Elderly Patients:Phenytoin clearance is decreased slightly in elderly patients and lower or less frequent dosing may be required. Pediatric: Intermittently, 6 in three doses equally divided doses, with subsequent dosage individualized to maintain plasma levels of 50 mg/mL. A recommended daily maintenance dosage is usually 6 to 8 mg/kg. Children over 6 years of age and adolescents may require the minimum adult dose of 300 mg/day.

HOW SUPPLIED
Extended Phenyltoin Sodium Capsules, USP 100 mg and 200 mg in gelatin capsules. In each extended release capsule, phenyltoin sodium is equivalent to 100 mg or 200 mg of the sodium salt. They are available in bottles of 100, 200, 500, and 1000.

Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Preserve in light-resistant containers. Protect from moisture.

MANUFACTURER
USP-SMITH LABORATORIES, INC.

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Made in Israel

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MEDICATION GUIDE
Extended Phenyltoin (fen’ i toin) Sodium Capsules, USP

Read this Medication Guide before you start taking Extended Phenyltoin Sodium Capsules, USP and each time you get a refill. There may be new information about the use of this medicine. This Medication Guide should be given to you by your doctor or pharmacist if you are already taking this medicine. If you are a new patient and your doctor has prescribed this medicine, read the Medication Guide before you start taking the medicine. It is important for you to read this information so you understand why you are taking the medicine and how it will help you.

Phenytoin can cause serious side effects including:

1. Like other antiepileptic medicines, phenytoin may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

• thoughts about suicide or dying
• attempts to commit suicide
• new or worse depression
• new or worse anxiety
• feeling sad or绝望
• trouble falling or sleeping
• increased alcohol or drug use
• thinking about self-harm or suicide

Call your healthcare provider right away if you have any of the symptoms listed above.

What is Phenytoin?Phenytoin is a prescription medicine used to treat tonic-clonic (grand mal) complex partial (temporal lobe) seizures, and to prevent and treat seizures that happen during or after surgery.

Who should not take Phenytoin?

• are allergic to phenytoin or any of the ingredients in Extended Phenyltoin Sodium Capsules, USP. See the end of this leaflet for a complete list of ingredients in Extended Phenyltoin Sodium Capsules, USP.
• have had an allergic reaction to GBEPHY (phenytoin), PHENAGEL (phenytoin), or REGIDROG (phenytoin).

Take phenytoin as directed.

What should I tell my healthcare provider before taking Phenytoin?

It is important for you to talk to your healthcare provider before you start taking phenytoin. It is especially important if you are a new patient and your doctor has prescribed this medicine. It is important for you to tell your healthcare provider if:

• you have or have had osteoporosis or broken bones.
• you have had kidney disease.
• you have or have had periodontal disease.
• you have or have had depression, mood disorders, or suicidal thoughts or behavior.
• you are pregnant or plan to become pregnant. If you become pregnant while taking phenytoin, tell your healthcare provider right away.
• you are breast-feeding or plan to breast-feed. Phenyltoin can pass into breast milk. You and your healthcare provider should decides if you will take phenytoin or breast-feed. You should not breast-feed if you are taking this medicine.

Tell your healthcare provider about all the medicines you take. This includes prescription and non-prescription medicines, vitamins, and herbal supplements. Tell your healthcare provider if you smoke or use illegal drugs.

Tell your healthcare provider if you are taking or plan to take any other medicines. This includes prescription and non-prescription medicines, vitamins, and herbal supplements. It is especially important if you take medicines for heart disease, diabetes, or asthma.

How should I take Phenytoin?Phenytoin is usually taken as prescribed. Your healthcare provider will tell you how much Phenyltoin to take. Your healthcare provider or pharmacist can give you more detailed information about how to take phenytoin.

Phenytoin can cause changes in your bowel movements and irritate your throat and mouth. If you take any of these medicines, they may affect how phenytoin works or increase your risk of serious side effects.

Do not take any phenytoin without first talking to your healthcare provider. Stopping a seizure medicine suddenly in a patient with epilepsy can cause seizures that will not stop (status epilepticus) which can be life-threatening.

Tell your healthcare provider if you have any of the symptoms listed above.

What is the most important information I should know about Phenyltoin?Phenytoin can cause serious or life-threatening side effects including:

• swelling of your hands and feet (edema), or other parts of your body
• numbness, tingling, or weakness in your hands or feet
• rash
• itching
• unusual bleeding or bruising
• severe muscle pain
• fever, chills, shaking, or feeling very sick
• bruising or bleeding
• change in color or feeling of your skin or hair
• the loss of appetite
• vision problems
• confusion, agitation, acting aggressive, being angry, or violent
• memory problems
• the loss of interest or enjoyment in things you used to enjoy
• new or worse depression
• thoughts or actions, your healthcare provider may check for other causes.

Precautions may have the following side effects:

• diarrhea (chronic or decreases) should be involved with at least 6 hours to 7 days, so they may be involved with chronic diarrhea or increased blood levels with phenytoin changes in