

Palmetto State Pharmaceuticals

Patient Drug Education

ENTEX PSE 400-120 CAPSULE

USES:

Guaifenesin/pseudoephedrine is used for the temporary relief of nose/sinus/ear congestion and cough with phlegm caused by the common cold, allergies, or infection. Pseudoephedrine is called a sympathomimetic and works by decreasing the swelling of nose and ear tissues and opening nose passages. Guaifenesin is called an expectorant. It works by making phlegm in the breathing tubes more liquid. This helps the cough to clear phlegm better.

HOW TO TAKE THIS MEDICATION:

HOW TO USE: Take this medication by mouth, usually every 12 hours with a full glass of water or as directed by your doctor. If stomach upset occurs, take with food or milk. Sustained-release products should be swallowed whole. Do not crush, chew, or split this medication. Doing so can destroy the long action of the drug and may increase side effects. Dosage is based on your age, medical condition and response to therapy. If this medication does not require a prescription from your doctor, follow the specific dosing instructions on the packaging to find the correct dose for your age. If your doctor directs you to take this medication daily, take it regularly to get the most benefit from it. To help you remember, take it at the same time(s) each day. If your symptoms do not improve after 7 days, if they worsen, or if you develop a fever/chills, contact your doctor. Do not take more medication than is recommended.

SIDE EFFECTS:

Mild stomach upset, trouble sleeping, dizziness, lightheadedness, headache, nervousness, fast heartbeat, loss of appetite, shaking, or unusual sweating may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. This product may reduce blood flow to your hands and feet, causing them to feel cold. Smoking may worsen this effect. Dress warmly and avoid tobacco use. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: fast/irregular heartbeat, severe/uncontrolled shaking, difficulty urinating, decreased sexual ability. Tell your doctor immediately if any of these rare but very serious side effects occur: chest pain, seizures, mental/mood changes (e.g., anxiety, panic, hallucinations). A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, tell your doctor or pharmacist.

PRECAUTIONS:

Before taking this medication, tell your doctor or pharmacist if you are allergic to pseudoephedrine or guaifenesin; or if you have any other allergies. Also tell your doctor if you have had a negative reaction to other sympathomimetics (e.g., ephedrine, phenylephrine). This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: severe high blood pressure, heart disease (e.g., severe coronary artery disease, angina, heart failure), certain types of fast heart rhythm problems (e.g., atrial fibrillation/flutter, paroxysmal supraventricular tachycardia-PSVT), a certain slow heart rhythm problem (sinus bradycardia), closed-angle glaucoma, difficulty urinating (e.g., due to enlarged prostate). Before using this medication, tell your doctor or pharmacist your medical history, especially of: stroke, high blood pressure, chest pain (angina), heart attack, smoking, long-term breathing problems (e.g., asthma, chronic bronchitis, emphysema), cough with large amounts of phlegm, mental/mood disorders (e.g., anxiety, bipolar disorder, mania), epilepsy/seizure problems, certain blood vessel problems (e.g., Raynaud's disease, peripheral vascular disease), overactive thyroid (hyperthyroidism), low blood flow to the brain (cerebral insufficiency), diabetes, difficulty sleeping. This drug may make you dizzy or lightheaded; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially dizziness and lightheadedness. Caution is advised when using this product in infants and children because they may be more sensitive to its side effects, especially excitation, agitation, and increased blood pressure. The extended-release preparations containing 120 and 240 mg of pseudoephedrine should not be administered to patients younger than 12 years of age. During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. The pseudoephedrine in this product passes into breast milk. It is not known whether guaifenesin passes into breast milk. Breast-feeding while using this product is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. This drug should not be used with the following medications because very serious interactions may occur: MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine). Avoid taking MAO inhibitors within 2 weeks before, during, and after treatment with this medication. In some cases a serious, possibly fatal drug interaction may occur. If you are currently using any of these medications, tell your doctor or pharmacist before starting this product. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: other decongestants (taken by mouth or sprayed into the nose), products containing caffeine, some blood pressure medications (e.g., beta blockers, calcium channel blockers, reserpine, guanethidine, methyl dopa, mecamlamine), tricyclic antidepressants (e.g., nortriptyline, amitriptyline), digoxin. Pseudoephedrine may worsen the serious side effects of some medications used for migraine headaches (e.g., sumatriptan, naratriptan, zolmitriptan, ergotamine). Consult your pharmacist or doctor for more details. Check the labels on all your medicines (e.g., cough-and-cold products, diet aids) because they may contain ingredients that could increase your heart rate or blood pressure. Ask your pharmacist about the safe use of those

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products before using them. Pseudoephedrine and guaifenesin are available in both prescription and nonprescription products. Check the labels of all your medications carefully to make sure you are not taking more than one product containing these medications. The guaifenesin in this product can affect the results of certain lab tests (e.g., uric acid levels, 5-hydroxyindoleacetic acid levels, vanillylmandelic acid levels), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

NOTES:

Do not share this medication with others. Drink plenty of fluids while taking this medication unless your doctor instructs you otherwise. This may help to relieve congestion. This medication is for temporary use only. Do not use for more than 7 days without first consulting your doctor.

MISSED DOSE:

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature at 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.