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Sinutrol PE

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- **ActiveIngredient:**
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Description

Side Effects Drowsiness, dizziness, blurred vision, upset stomach, nausea, nervousness, or dry mouth/nose/throat may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. If your doctor has prescribed this medication, remember that your doctor 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 right away if you have any serious side effects, including: mental/mood changes (such as confusion, hallucinations), shaking, trouble urinating, fast/slow/irregular heartbeat, seizure. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses This combination medication is used to temporarily treat symptoms caused by the common cold, flu, allergies, or other breathing illnesses (such as sinusitis, bronchitis). Decongestants help relieve stuffy nose, sinus, and ear congestion symptoms. Acetaminophen (APAP) is a non-aspirin pain reliever and fever reducer. Antihistamines help relieve watery eyes, itchy eyes/nose/throat, runny nose, and sneezing. Cough-and-cold products have not been shown to be safe or effective in children younger than 6 years. Do not use this product to treat cold symptoms in children younger than 6 years unless specifically directed by the doctor. Some products (such as long-acting tablets/capsules) are not recommended for use in children younger than 12 years. Ask your doctor or pharmacist for more details about using your product safely. These products do not cure or shorten the length of the common cold and may cause serious side effects. To decrease the risk for serious side effects, carefully follow all dosage directions. Do not use this product to make a child sleepy. Do not give other cough-and-cold medication that might contain the same or similar ingredients. Ask the doctor or pharmacist about other ways to relieve cough and cold symptoms (such as drinking enough fluids, using a humidifier or saline nose drops/spray). How to use Sinutrol PE If you are taking the over-the-counter product, read and follow all directions on the package label. If your doctor has prescribed this medication for you, take as directed by your doctor. If you have any questions, consult your doctor or pharmacist. Take this medication by mouth with or without food or as directed by your doctor. If stomach upset occurs, it may help to take this

medication with food or milk. Drink plenty of fluids when you use this medication unless otherwise directed by your doctor. The fluid will help loosen the mucus in your lungs. If you are using the liquid form of this medication, carefully measure the dose using a special measuring device/spoon. Do not use a household spoon because you may not get the correct dose. If your liquid form is a suspension, shake the bottle well before each dose. If you are taking the extended-release capsules, swallow them whole. Do not crush or chew extended-release capsules or tablets. Doing so can release all of the drug at once, increasing the risk of side effects. Also, do not split extended-release tablets unless they have a score line and your doctor or pharmacist tells you to do so. Swallow the whole or split tablet without crushing or chewing. If you are taking the chewable form of this medication, chew it thoroughly before swallowing. The dosage is based on your age, medical condition, and response to treatment. Do not increase your dose, take it more often, or use it for a longer time than directed. Do not give children medicines labeled only for adults. Tell your doctor if your condition lasts for more than 1 week, if it gets worse, or if it occurs with headache that doesn't go away, rash, or fever lasting more than 3 days. These may be symptoms of a serious medical problem and should be checked by a doctor. Depending on the symptoms being treated, you may need to contact your doctor earlier than 1 week, if they last or get worse. Check your specific package label for when to contact your doctor.

Warnings One ingredient in this product is acetaminophen. Taking too much acetaminophen may cause serious (possibly fatal) liver disease. Adults should not take more than 4000 milligrams (4 grams) of acetaminophen a day. People with liver problems and children should take less acetaminophen. Ask your doctor or pharmacist how much acetaminophen is safe to take. Do not use with any other drug containing acetaminophen without asking your doctor or pharmacist first. Acetaminophen is in many nonprescription and prescription medications (such as pain/fever drugs or cough-and-cold products). Check the labels on all your medicines to see if they contain acetaminophen, and ask your pharmacist if you are unsure. Get medical help right away if you take too much acetaminophen (overdose), even if you feel well. Overdose symptoms may include nausea, vomiting, loss of appetite, sweating, stomach/abdominal pain, extreme tiredness, yellowing eyes/skin, and dark urine. Daily alcohol use, especially when combined with acetaminophen, may damage your liver. Avoid alcohol.

Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug are: ketoconazole, levoketoconazole. Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before treatment with this medication. Ask your doctor when to start or stop taking this medication. Tell your doctor or pharmacist if you are taking other products that cause drowsiness such as opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or other antihistamines (such as cetirizine, diphenhydramine). The ingredients in this product are available in many prescription and nonprescription products. Check the labels on all your medicines (such as pain/fever drugs, diet aids, or cough-and-cold/allergy products) because they may contain the same or similar ingredients. Using these drugs along with this product could increase side effects (such as fast heartbeat, increased blood pressure, or drowsiness). Ask your pharmacist about using those products safely. Do not use with any other antihistamines applied to the skin (such as diphenhydramine cream, ointment, spray) because increased side effects may occur. This medication may interfere with certain lab tests (such as urine drug screening tests, urine 5-HIAA, allergy skin test), possibly causing false test results. Make sure lab personnel and all your doctors know you use this drug.

Precautions Before taking this product, tell your doctor or pharmacist if you are allergic to any of its ingredients; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. If you have any of the following health problems, consult your doctor or pharmacist before using this medication: breathing problems (such as asthma, emphysema), diabetes, glaucoma, heart problems, high blood pressure, kidney problems, liver disease, seizures, stomach/intestinal problems (such as blockage, constipation, ulcers), overactive thyroid (hyperthyroidism), urination problems (such as trouble urinating due to enlarged prostate,

urinary retention). This drug may make you dizzy or drowsy or blur your vision. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness or clear vision until you can do it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Some brands of this product may contain sugar, alcohol, or aspartame. Caution is advised if you have diabetes, alcohol dependence, liver disease, phenylketonuria (PKU), or any other condition that requires you to limit/avoid these substances in your diet. Ask your doctor or pharmacist about using this product safely. Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Children may be more sensitive to the side effects of this drug. In young children, antihistamines may cause agitation/excitement instead of drowsiness. Older adults may be more sensitive to the side effects of this drug, especially dizziness, drowsiness, confusion, constipation, trouble urinating, fast/irregular heartbeat, or trouble sleeping. Dizziness, drowsiness, trouble sleeping, and confusion can increase the risk of falling. During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. This medication may pass into breast milk and may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding. Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: nausea, vomiting, loss of appetite, sweating, stomach/abdominal pain, extreme tiredness, agitation, confusion, flushing, hallucinations, yellowing eyes/skin, dark urine, seizures. In children, excitement may occur first, and may be followed by: loss of coordination, drowsiness, loss of consciousness, seizures. Keep all medical and lab appointments. If you are taking this product on a regular schedule and miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. Store at room temperature away from light and moisture. Do not store in the bathroom. Do not freeze liquid forms of this medication. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Side Effects

Uses

Interactions

Other Details
