



Rx Focus

Tougher Restrictions on Pseudoephedrine Products

Pseudoephedrine is a common nasal decongestant found in many over the counter cough and cold products. It is sold alone in the product Sudafed® and in combination with pain relievers, cough suppressants, and antihistamines. The product has a mild stimulatory effect, which helps clear the sinuses and is generally safe to use for its intended purposes.

Pseudoephedrine (PSE) can be converted into a dangerous, highly potent illicit stimulant, methamphetamine (also known as "speed," "crank," "ice," and "crystal meth"), in illegal laboratories that operate for such a purpose. Often, these laboratories are established in a residential setting. Meth labs have been found in apartments, hotel rooms, rented storage spaces, and trucks. The laboratories not only pose a threat to the end users of the drug, but also to the environment and their neighbors. This is because the chemicals used in the illegal conversion of pseudoephedrine to methamphetamine are both toxic and explosive. First responders to meth lab fires and explosions are often injured by the toxic chemicals. Furthermore, the production of one pound of methamphetamine yields between five and seven pounds of toxic waste. This waste is often disposed of down household drains, in fields or yards, or on rural roads.

The Federal government has taken several steps to restrict the availability of pseudoephedrine products to legitimate use. The first such law was the Methamphetamine Control Act of 1996. The law put restrictions on the chemicals used in the manufacturing of methamphetamine, as well as putting small restrictions on the amount of pseudoephedrine, ephedrine, or phenylpropanolamine (PPA) that could be purchased at one time. It also established stricter penalties for trafficking methamphetamine or the products used in its production. Another important law is the Methamphetamine Anti-Proliferation Act of 2000, which strengthened sentencing guidelines and provided training to law enforcement investigators on how to investigate and handle clandestine meth labs. It further restricted the chemical ingredients used in the production of methamphetamine.

The Renewal of the USA PATRIOT Act in 2005 contained the Combat Methamphetamine Epidemic Act, which imposes further restrictions seeking to reduce illegal methamphetamine production and drug abuse.

The new law restricts the sale of necessary ingredients to make methamphetamine. Specifically, a quantity limit will be placed on the amount of pseudoephedrine a consumer can purchase per time period, the product will be moved behind the counter, and

the consumer will be required to present identification prior to purchase.

This means that pseudoephedrine products may no longer be available from the shelf at your local drug store or supermarket. You may have to ask the pharmacist should you need to purchase the product.

Specific restrictions will be as follows: Starting April 8, 2006, consumers are limited to the purchase of 3.6 grams daily (about 120 regular strength pseudoephedrine tablets or 15 24-hour pseudoephedrine tablets). On a monthly basis, consumers may purchase up to 9 grams of pseudoephedrine (300 regular strength tablets, 37 24-hour tablets). Purchases from mail-order suppliers will be limited to 7.5 grams per 30 days (250 regular strength tablets, 31 24-hour tablets). These are the non-prescription limitations, no limitation will be placed on obtaining pseudoephedrine with a prescription from your physician. As of this date, pseudoephedrine must also be packaged in blister packs and not in bulk bottles.

Starting September 30, 2006, purchasers will be required to show identification to obtain non-prescription pseudoephedrine products. This will improve the ability to restrict quantities to those previously outlined.

New products containing phenylephrine (PE), a chemical with similar decongestant properties to pseudoephedrine, but unable to be converted to methamphetamine, are being introduced. These products, such as Sudafed PE®, are not restricted like pseudoephedrine and may be purchased directly from the shelf.

Though they may be a minor inconvenience to consumers, hopefully these new restrictions on pseudoephedrine will reduce the supply of precursors to methamphetamine, and the dangers of illegal meth production and use along with it.

References:

1. Pharmacist's Letter/Prescriber's Letter 2006; 22(4):220413.
2. ONDCP Drug Policy Information Clearinghouse Fact Sheet: Methamphetamine
3. Fed Regist. 2002 Mar 28;67(60):14853-62.
4. USA PATRIOT Improvement and Reauthorization Act of 2005, HR. 3199, 109d Cong., 2nd Sess. (2005).



Industry Focus

Phenylpropanolamine (PPA) Update

The FDA issued a request in November 2000 urging companies to voluntarily withdraw products containing PPA due to an increased risk of hemorrhagic stroke in women. Men may also be at risk. Though the risk of hemorrhagic stroke is low, the FDA

has advised consumers not to use products containing PPA. The FDA has ruled these products as "not safe and effective," however, some products may still be available for purchase over-the-counter. Consumers are urged to read the labels of OTC cough and cold products or ask a pharmacist to assure they do not contain PPA.



New Drug Approvals

Zegerid™ Chewable Tablets

Approved: 03/24/2006

Chemical Name: Omeprazole/Sodium Bicarbonate

Manufacturer: Santarus

Approved Indications: GERD

Therapeutic Class: Proton Pump Inhibitor

Average Wholesale Price: unavailable at this time

Notes: May be more cost-effective and palatable than extemporaneously prepared omeprazole suspensions made by pharmacists.

YAZ® Tablets

Approved: 03/16/2006

Chemical Name: Drospirenone 3 mg/ Ethinyl Estradiol 0.02 mg

Manufacturer: Berlex Labs

Therapeutic Class: Oral Contraceptive

Approved Indication: Prevention of Pregnancy

Average Wholesale Price: \$49.94/cycle

Notes: A 24-day regimen that offers lower estrogen than most commercially available oral contraceptives. As a result, only a 4-day "wash-out" period is required rather than the usual 7 of most oral contraceptives.



New Generic Drug Approvals

Zonisamide Capsules

Approved: 03/17/2006

Manufacturers: Sun Pharmaceuticals

Brand Name Equivalent: Zonegran®

Approved Indication: Lennox-Gastaut syndrome, Partial seizure treatment

Terbinafine Tablets

Approved: 03/28/2006

Manufacturers: Watson Labs

Brand Name Equivalent: Lamisil®

Approved Indication: Fungal infections of fingernails and toenails

Notes: Tentative Approval

Rivastigmine Capsules

Approved: 03/29/2006

Manufacturers: Sun Pharmaceuticals

Brand Name Equivalent: Exelon®

Approved Indication: Treatment of Alzheimer's Disease

Notes: Tentative Approval



Recipe X-Change

The National Cancer Institute recommends eating 5 servings of fruits and vegetables every day. Studies by the U.S. Department of Health and Human Services, U.S. Department of Agriculture, and the National Academy of Sciences suggest that the nutritional goodness of fruits and vegetables, with a diet that is low in fat, saturated fat and cholesterol and that contains plenty of whole-grain breads and cereals, may decrease the risk of heart disease and cancer.

A major reason to eat more fruits and vegetables is their nutritional value. Unless baked in a pie or dripping in butter, most are low in fat and calories – except avocados, coconut and olives, all of which contain fat naturally. Many are excellent sources of the important vitamins A and C and provide ample fiber. In addition, many fruits and vegetables, particularly dried beans and peas, are significant sources of folate, a B vitamin that can help reduce the risk of certain serious and common birth defects.

Here's what the National Cancer Institute recommends as a serving of fruit and vegetables:

- 1 medium fruit or 1/2 cup of small or cut-up fruit
- 3/4 cup (180 milliliters) of 100 percent juice
- 1/4 cup dried fruit
- 1/2 cup raw non-leafy or cooked vegetables
- 1 cup raw leafy vegetables (such as lettuce)
- 1/2 cup cooked beans or peas (such as lentils, pinto beans, and kidney beans)

Marinated Fresh Vegetable Salad

Fresh Raw Vegetables:	Small & Tender:
Broccoli	Cucumbers
Cauliflower	Yellow squash
Green onions	Zucchini
Green peppers	Tomatoes, quartered
	1 tsp. salt

Dressing:

1 c. vinegar

1/2 c. sugar (sweetener or honey may be used)

Chopped **fresh** herbs: chives, parsley, dill leaves, basil

Use any combination of **fresh** raw vegetables, slice or cut in sizes or shapes you desire. Combine all except tomatoes. Add these just before serving. Mix dressing ingredients making sure sugar is dissolved. Pour dressing over vegetables, toss lightly. Chill 2 hours before serving.



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