



Rx Focus

FDA Looking into Link Between Blindness and Use of Impotence Medications

About 30 million men in the United States have impotence. Erectile Dysfunction (ED), also called impotence, is the persistent or repeated inability, for at least 3 months, to attain and/or maintain an erection sufficient for satisfactory sexual performance.

Recently, there have been questions concerning sudden blindness with use of erectile dysfunction drugs. While Viagra (sildenafil—Pfizer) is known to produce blurred vision and changes in blue-green color vision, the FDA is working with the company to analyze 38 reports of Non-Arteritic Anterior Ischemic Optic Neuropathy (NAION) in men taking that drug. NAION is caused by lack of blood flow to areas of the retina and optic nerve resulting in patches of blurred vision and even permanent vision loss in parts of the visual field. The symptoms usually start within 24 hours of taking the drug. As of May 27, 2005, the U.S. Food and Drug Administration was looking into some 50 reported cases of men blinded after using Viagra. Dr. Howard Pomeranz, a neuro-ophthalmologist at the University of Minnesota appears to be the first doctor to have made this connection back in 1998. He said it made sense that Viagra, which alters blood flow in key parts of the body, could also affect circulation to the optic nerve. However, Pfizer countered that NAION shares a number of risk factors common to men with ED. These include persons over the age of 50, hypertension, hypercholesterolemia, and diabetes, which make it difficult to associate ED medications

with the effect. Recently, Pfizer told CBS its Viagra studies show no reports of blindness and said there is no evidence demonstrating that NAION occurs more frequently in men taking Viagra versus men of similar age and health who do not take Viagra. In addition, Pfizer states that a review of 103 Viagra clinical trials, involving 13,000 patients, found no reports of NAION.

Levitra (vardenafil—Bayer) was involved in four cases of NAION, while one patient had the condition after taking Cialis (tadalafil—Lilly). Because these two agents are more specific for the phosphodiesterase type 5 isoenzyme involved in erectile dysfunction, they do not have much effect on the type 6 isoenzyme found in the eye, and changes in color vision have been reported less frequently than with Viagra.

Selecting a treatment for ED is a personal decision. Each physician will evaluate each patient to determine if that patient has a medical condition that might need attention before receiving treatment for ED. Caution is advised in men having serious forms of heart disease such as a recent heart attack or stroke (within the past 2 or 3 months); certain heart rhythm problems; severe (unstable) angina; untreated or severe high blood pressure; severe heart failure; and/or severe heart valve disease (aortic stenosis).

Other men with heart problems also may need to be evaluated by a cardiologist to determine if it is safe for them to be sexually active and use any medication to treat their ED. If a patient has chest pain, dizziness or nausea while taking medications for ED, it is imperative that the physician be contacted immediately. Oral phosphodiesterase inhibitors, i.e., Viagra, are appropriate only for a select population of patients. Coverage of impotence medications by CBCA Rx is based on each group's benefit design. CBCA Rx offers options for groups to elect coverage with quantity limits, require prior authorization, or exclude all medications in this therapeutic class.

June Health Observances

Fireworks Safety Month

Sponsor: Prevent Blindness America
Website: www.preventblindness.org

National Safety Month

Sponsor: National Safety Council
Website: www.nsc.org

National Scleroderma Awareness Month

Sponsor: Scleroderma Foundation
Website: www.scleroderma.org



New Drug Approvals

Focalin XR Capsules

Approved 5/26/2005

Chemical Name: Dexmethylphenidate hydrochloride

Manufacturer: Novartis Pharmaceuticals

Approved Indication: Treatment of ADHD

Average Wholesale Price: \$3.39/Capsule (\$101.70/Month)

Special Notes:

Focalin XR will be available in 5mg, 10mg, and 20mg Capsules

Zemplar Capsules

Approved 5/31/2005

Chemical Name: Paricalcitol

Manufacturer: Abbot Labs

Approved Indication: Prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (stage 3 and 4).

Average Wholesale Price: 1mcg \$6.75/capsule, 2 mcg

\$13.50/capsule, 4 mcg \$27.00/capsule.

Special Notes: Cost of therapy will vary based upon dosing schedule and baseline intact parathyroid hormone (iPTH) levels.



New Generic Approvals

Carbilev (Carbidopa/Levodopa)

Approved: 6/10/2005

Manufacturer: Ranbaxy

Brand Name Equivalent: Sinemet Tablets

Approved Indication: Treatment of Parkinson's Disease

Zolpidem Tartrate

Approved: 5/26/2005

Manufacturer: Biovail

Brand Name Equivalent: Ambien

Approved Indication: Sleep Disorders

Notes: Tentative Approval

Fenofibrate

Approved: 5/13/2005

Manufacturer: Teva Pharmaceuticals

Brand Name Equivalent: Tricor

Approved Indication: Cholesterol Reduction

Clarithromycin

Approved: 5/31/2005

Manufacturer: Dava Pharmaceuticals

Brand Name Equivalent: Biaxin FilmTabs

Therapeutic Category: Antibiotic



Summer Survival Tips

1. Plan to refill medications one week prior to leaving on vacation. Make sure there is an adequate supply for the duration of the trip.
2. Provide children with extra asthma and allergy medication for emergency supply when going off to camp.
3. Do not forget to use and bring an insect repellent with DEET on vacation. Use of DEET will lower the risk of infection from insect bites. Do not use products containing greater than 30% DEET in children.
4. Be sure to always have an Emergency Bee Sting kit available if you have a severe allergic reaction to bees.
5. Use and bring Suntan Lotion on vacation. Choose a product that has an SPF (Sun Protection Factor) of 15 or higher with broad-spectrum protection against UVA and UVB. Reapply frequently for maximum protection. Wear sunglasses and hats to minimize exposure to areas without sunscreen.
6. Avoid heat exhaustion and heat stroke by limiting activities during extreme heat and maintaining proper hydration.
7. Plan ahead by scheduling a back to school health exam for children before the end of the summer. MD offices may run out of appointments and certain vaccines may require multiple doses.
8. Make sure your cooler will keep foods at 40°F, or plan foods that are less perishable, such as luncheon meats, cheese, peanut butter, etc.
9. Potato, macaroni and other salads containing milk, meat or eggs should be transported on ice. At a picnic, consider nesting the salad bowl in a larger bowl filled with ice. Immediately store leftovers in an ice chest. Food left out for more than two hours should be discarded. Consider serving potato chips instead of potato salad.
10. Always wear a life-preserver in when on a lake, river or ocean while boating, water skiing, jet skiing or tubing.
11. Do not let children play with fireworks. Observe fireworks from a safe distance only at sanctioned events.



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