

- Rx Focus - Guarding Against Acetaminophen Overdose
- State & Federal Updates
- New Drug Approvals
- New Generic Approvals



Rx Focus

Guarding Against Acetaminophen Overdose

It is important to be aware that unintentional acetaminophen overdoses are not that uncommon. Acetaminophen is the active ingredient in Tylenol®, and acetaminophen is often an ingredient in many over-the-counter and prescription cough, cold and pain medications.

The maximum recommended daily dose of acetaminophen is 4000mg (or 4 grams) for adults and 50-75 mg/kg per day for children. Doses above these amounts have been associated with liver toxicity. According to the 2002 Annual Report of the American Association of Poison Control Centers, there were almost 120,000 reported cases of human poison exposure involving acetaminophen.

Symptoms of acetaminophen toxicity include nausea, vomiting, malaise, abdominal pain, liver tenderness, liver or kidney failure, jaundice, confusion, and coma. Those individuals who fast or have inadequate protein intake, and those consuming three or more alcoholic beverages per day are at an increased risk of developing liver toxicity from acetaminophen. (These individuals should limit their total daily acetaminophen intake to less than the recommended maximum – a 2 gram limit has been suggested but, avoiding regular or excessive use of acetaminophen would be best.)

It is important to be aware of the following situations that can result in unintentional overdoses of acetaminophen:

- Taking more medication than is prescribed.
- Taking multiple over-the-counter or prescription products containing acetaminophen.
- Parents getting the infant (100 mg/ml) and pediatric (32 mg/ml) concentrations of acetaminophen confused.
- Not understanding the seriousness of acetaminophen toxicity.
- Not recognizing the symptoms of acetaminophen toxicity.

To further protect you and your loved ones from acetaminophen overdoses, the following steps can be taken:

- Always ask a healthcare provider before combining cough & cold and pain medications (over-the-counter and prescription).
- Never take more medication than is prescribed or take it more often than prescribed.
- Post the local poison control center phone number or National Poison Hotline (800-222-1222) in your home.
- Store all medications out of the reach of children.

Reference:

Pharmacist's Letter, Detail-Document #191115, by Ellen Whipple Guthrie, Pharm.D., November 2003



State & Federal Updates

Drug Benefit Provisions of New Medicare Legislation

As many people are aware, new Medicare legislation was passed at the end of last month. The main drug benefit will begin in 2006, with an interim program in effect in 2004 and 2005.

Beginning in 2004, older Americans will be able to buy a discount prescription card for \$30 a year. It is estimated that this card will save seniors anywhere from 15% to 25% off the cost of prescription drugs. In addition, low-income seniors will get an annual subsidy of \$600 to further defray medication costs.

The main drug benefit will begin in 2006. Medicare beneficiaries will have the option of either joining a private health plan that provides drug coverage or signing up for a stand-alone drug plan. The estimated premium would be \$420 per year (\$35 per month). In addition, after meeting a \$25 deductible, insurance would pick up 75% of prescription costs up to \$2,250.

Other provisions of the main drug benefit include:

- Catastrophic Coverage – when medication costs reach \$5,100, insurance will cover 95% of drug costs or require a modest copay.

- Low-Income Subsidies – seniors earning up to \$12,123 a year would have the premium, deductible and coverage gap waived. In order to qualify, seniors could have no more than \$6,000 in assets (other than a house). Subsidies would be phased out between annual incomes of approximately \$12,123 and \$13,500.
- Coverage Gap – no coverage for medication costs between \$2,250 and \$5,100.
- Retiree Coverage – employers maintaining drug coverage for retirees will be eligible for tax-free subsidies.

Reference:

1. www.peacehealth.org/Oregon/NewsMedicare_Nov03.htm



New Drug Approvals

Namenda 5mg and 10mg Tablets

Approved 10/16/03

Chemical Name: memantine hydrochloride

Manufacturer: Forest Laboratories

Therapeutic Class: N-methyl-D-aspartate (NMDA) receptor blocker

Approved Indications: Treatment of moderate to severe Alzheimer's disease.

Average Wholesale Price: \$2.33 per unit (both strengths)

Special Notes: First drug in new class for treatment of Alzheimer's disease.

Cialis 5mg, 10mg and 20mg Tablets

Approved 11/21/2003

Chemical Name: tadalafil

Manufacturer: Eli Lilly and Company

Approved Indication: Treatment of Erectile Dysfunction

Other Drugs in Class: Levitra, Viagra

Average Wholesale Price: \$10.12 per unit (all strengths)

Special Notes: For plans covering this class of medication, same quantity limits as for Levitra and Viagra will apply.

Restylane Injectable Gel

Approved 12/12/03

Chemical Name: Hyaluronic Acid

Manufacturer: Q-Med AB of Sweden

Approved Indication: Treatment of facial wrinkles.

Average Wholesale Price: Not known at this time

Special Notes: Because of its cosmetic indication, and because it is not a self-injectable product, this medication will be excluded from coverage on all of our plans.



New Generic Approvals

Betamethasone Dipropionate Cream 0.05%

Approved 12/9/03

Brand Name Equivalent: Diprolene® AF Cream

Manufacturers: Clay-Park Labs, Taro Pharmaceuticals, Altana Inc.

Bupropion Hydrochloride Extended-Release Tablets, 100mg

Approved 11/25/03

Brand Name Equivalent: Wellbutrin SR 100mg

Manufacturer: Eon Labs

Fosinopril Sodium Tablets, 10mg, 20mg and 40mg

Approved 11/25/03

Brand Name Equivalent: Monopril®

Manufacturer: Teva Pharmaceutical Industries Ltd.



675 Foxon Road, Suite 204
East Haven CT 06513
Phone: (800) 936-1193
Fax: (203) 468-8416