



Rx Focus

Preventing Medication Poisonings in Toddlers

In the year 2000, 40% of the poisonings reported to the American Association of Poison Control Centers occurred in toddlers two years of age or younger. Because of their lower body weight, ingestion of small amounts of certain medications can be potentially fatal. Although all medications (prescription and over-the-counter) should be stored out of the reach of children, this is particularly critical for the following specific medications.

Iron preparations, both single-ingredient tablets and multivitamin preparations, are responsible for the largest number of fatal overdoses in children. The lethal dose for a toddler is approximately ten tablets. Until October of 2003, oral iron products containing 30mg or more of elemental iron were required to be blister packaged to reduce the risk of accidental poisonings. However, manufacturers sued the FDA for imposing this requirement and now, the packaging for iron preparations must simply state the following: "WARNING: Accidental overdose of iron-containing

products is a leading cause of fatal poisonings in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately."

The older antidepressant and antipsychotic agents can be lethal in small doses. This includes medications such as amitriptyline (Elavil®), imipramine (Tofranil®), desipramine (Norpramin®), loxapine (Loxitane®), chlorpromazine (Thorazine®) and thioridazine (Mellaril®).

Just one or two doses of antimalarials can be fatal if ingested by a toddler, e.g., chloroquine (Aralen®), hydroxychloroquine (Plaquenil®) and quinine. With hydroxychloroquine now being used in the treatment of lupus and rheumatoid arthritis, the risk of toddler poisonings is increased. (Many of these patients cannot open child-proof containers so, these medications are often stored in bottles that are easily opened.) Extreme caution is advised in households with toddlers.

One to two doses of a number of different cardiovascular drugs can be lethal to a toddler:

- Antiarrhythmic Agents: procainamide (Pronestyl®), disopyramide (Norpace®), flecainide (Tambacor®), quinidine
- High Blood Pressure Medications: beta-blockers (e.g., propranolol (Inderal®)); clonidine; calcium channel blockers (e.g., diltiazem (Cardizem®), nifedipine (Procardia®), verapamil (Isoptin®))

Certain hypoglycemic agents used in the treatment of diabetes can be lethal to toddlers following ingestion of just one dose. Examples would be chlorpropamide (Diabinese®) or glipizide (Glucotrol®).

Relatively small doses of opiate drugs (codeine, hydrocodone, methadone and morphine) can cause central nervous system depression and respiratory arrest resulting in death in small children. Diphenoxylate (an ingredient of Lomotil® - commonly used to treat diarrhea) can be hazardous to a toddler. Two tablets or teaspoonfuls of Lomotil® can be fatal.

Topical arthritis preparations containing camphor or methyl salicylate (oil of wintergreen) can pose a problem if ingested by a toddler. Less than two teaspoonfuls of Campho-Phenique® (10% camphor) can cause neurologi-

September Health Observances

Baby Safety Month – Sponsored by Juvenile Products Manufacturers Association www.jpma.org

Gynecologic Cancer Awareness Month – Sponsored by Gynecologic Cancer Foundation www.wcn.org

Healthy Aging Month – Sponsored by Educational Television Network, Inc. www.healthyaging.net

Leukemia & Lymphoma Awareness Month – Sponsored by The Leukemia & Lymphoma Society www.lls.org

National Cholesterol Education Month – Sponsored by National Heart, Lung, and Blood Institute www.nhlbi.nih.gov

National 5 A Day Month (*eat 5 or more servings of fruits and vegetables every day for better health*) – Sponsored by National Cancer Institute/Produce for better Health Foundation www.5aday.gov

Ovarian Cancer Awareness Month – Sponsored by The National Ovarian Cancer Coalition www.ovarian.org

Prostate Cancer Awareness Month – Sponsored by National Prostate Cancer Coalition www.pcacoalition.org

cal problems and potentially death in a toddler. (Aspirin, also a salicylate, requires ingestion of at least six extra-strength tablets by a toddler to pose problems.)

Other medications that can be fatal to toddlers following ingestion of very small amounts include theophylline and podophyllin 25%.

Because any of the medications listed above are commonly found in households with toddlers, it is important to remind parents and grandparents to keep the national poison control phone number 1-800-222-1222 by the phone. (Note that it is no longer recommended to keep Syrup of Ipecac at home in case of accidental poisoning. Refer to the February 2004 issue of RxHints for further details.)

References:

1. "Poisonings in Toddlers" by Neeta Bahal O'Mara, Pharm.D., BCPS, Pharmacist's Letter, Detail-Document #200807, August 2004
2. "Drugs Highly Toxic to Toddlers" by Dr. R. Iconis, Peds for Parents (www.pedsforparents.com)



Industry Report

Adult Indication for Adderall

Adderall XR[®] (mixed salts of a single-entity amphetamine), manufactured by Shire Pharmaceutical Group, is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). In August, 2004, the FDA approved Adderall XR[®] as a once-daily treatment for adults.

Studies have shown that approximately 4% of the adult population in the United States is affected by ADHD. Up until this recent FDA approval, the manufacturer was not able to promote Adderall XR[®] usage in adults even though many physicians have been prescribing the product for this "off label" use for quite some time. It is estimated that adults currently represent 15 to 20% of Adderall XR[®] total prescriptions.

Topamax[®] Approved for Migraine Prevention

On August 12, 2004, the FDA approved topiramate (Topamax[®]) for the prevention of migraine headaches in adults. Almost 14 million adults suffer from frequent or severe migraines in the United States. Many medications approved for migraine treatment are taken at the onset of a headache; however, there are now several prophylactic treatment options available. These medications, of which Topamax[®] is the newest, are aimed at reducing the frequency of attacks. (Topamax[®], manufactured by Ortho-McNeil, was initially approved as adjunctive therapy in the treatment of various seizure disorders.)

Zelnorm[®] Approved for Chronic Constipation

Zelnorm[®] (tegaserod), manufactured by Novartis, has been available in the United States since July of 2002 for

the short-term treatment of women with Irritable Bowel Syndrome (IBS) whose primary bowel symptom is constipation. On August 23, 2004, the FDA approved the use of tegaserod for the treatment of chronic idiopathic constipation in male and female patients less than 65 years of age. This approval is based on clinical studies that demonstrate that tegaserod is generally safe and well tolerated long-term.

(Please Note: The May 2004 issue of RxHints detailed additional new risk information that the FDA had Novartis add to Zelnorm[®] labeling last April regarding the side effects of diarrhea and ischemic colitis. CBCA Rx has updated the Zelnorm Prior Authorization (PA) guidelines, and Zelnorm will continue to require a PA prior to use.)



New Drug Approvals

Pentetate Calcium Trisodium Injection (Ca-DTPA) and Pentetate Zinc Trisodium Injection (Zn-DTPA)

Approved: 8/11/04

Manufacturer: Hameln Pharmaceuticals, GmbH

Approved Indication: Treatment of internal contamination with the radioactive elements americium, curium and/or plutonium. (Release of americium, curium and plutonium could occur from laboratory or industrial accidents or through terrorist attacks using "dirty bombs".)

Special Notes: Because both of these agents are administered by injection, they would not be covered CBCA Rx plans.

Gabapentin 100mg, 300mg, and 400mg Tablets

Approved: 4/28/2004, available on 8/18/2004

Manufacturer: IVAX\Goldline

Approved Indication: Seizures and Postherpetic Neuralgia.

Special Notes: Not a generic substitute for Neurontin[™] 100mg, 300mg and 400mg capsules.

Chemical Name: Ezetimibe/Simvastatin

Manufacturer: Merck & Co. and Schering-Plough Corp.

Therapeutic Class: Cholesterol absorption inhibitor/Statin

Approved Indication: Hyperlipidemia

Special Notes: Combination of Zocor and Zetia cholesterol medications.

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

