



!!!Happy New Year !!!

January 2011

Harlem Pharmacy Newsletter

!!! TOO MUCH TYLENOL® (ACETAMINOPHEN) CAN LEAD TO LIVER DAMAGE!!!

Acetaminophen, also known as APAP is one of the most widely used over-the-counter pain and fever medication. However, exceeding the maximum recommended dose of acetaminophen can cause serious liver injury—even death. Therefore, to promote the safe use of acetaminophen, the manufacturer, Johnson & Johnson's McNeil Consumer Healthcare, **have reduced the recommended maximum daily dose of Tylenol from 4g to 3g.** The recommended daily maximum dose of Tylenol (500mg tablet) has been reduced from 8 tablets per day (4,000mg) to 6 tablets per day (3000mg).

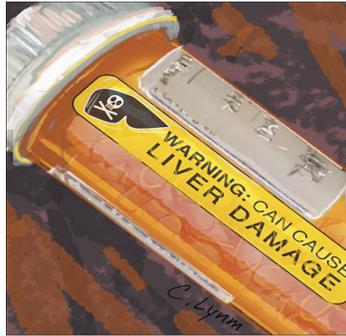
Starting Fall of 2011, the extra strength Tylenol products and the regular strength Tylenol products label will list the new maximum daily dose.

Besides Tylenol, acetaminophen is the active ingredient nonprescription products such as Sudafed, NyQuil and many other medicines used for headache, cold, sore throats etc. McNeil believes this action will reduce the risk of accidental acetaminophen overdose and liver damage.

For more information, visit:

<http://pharmacytimes.com/web-exclusives/Maximum-Dose-for-Tylenol-Lowered>

<http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm>



Over the years, FDA has received continued reports of acetaminophen associated liver injury and believes that reducing maximum daily dose will provide safe use of the drug amongst prescription users of acetaminophen combination products.

As of January 2011, the United States Food and Drug Administration proposed a boxed warning asking all manufacturers of prescription combination products containing acetaminophen to limit the amount of acetaminophen to be no more than 325mg per tablet or capsule. Manufacturers will also be required to label all prescription medications containing acetaminophen to warn of the potential risk for severe liver toxicity. Some of the prescription medications containing acetaminophen include:

- Opioids such as codeine (Tylenol with codeine)
- Percocet (oxycodone)
- Vicodin (hydrocodone)

Over the years, FDA has received continued reports of acetaminophen associated liver injury and believes that this action will provide safe use of the drug amongst prescription users of acetaminophen combination products.

This action taken by the FDA is for prescription products only and will not affect OTC acetaminophen products.

Pharmacy requested that Acetaminophen orders be changed in QuadraMed in order to reduce the risk of acetaminophen associated liver injury (see below)

BEFORE

1	Oral
2	Tablet (325 mg)
3	325 mg tab po q ___h prn ___
4	650 mg tab po q 4h prn ___
5	650 mg tab po q 4h prn pain
6	650 mg tab po q 4h prn temperature > ___
7	650 mg tab po q 6h prn ___
8	650 mg tab po q 6h prn pain
9	650 mg tab po q 6h prn temperature > ___
10	Caplet (500 mg)
11	1000 mg caplet po q6h prn if pain or temperature ___
12	1000 mg caplet po q4h prn ___
13	1000 mg caplet q___h prn if fever or temperature ___
14	Suspension (160 mg/5 mL)
15	160 mg (5 mL) po q___h prn if temperature > 102

AFTER

1	Oral
2	Tablet (325 mg)
3	325 mg tab po q ___h prn ___
4	650 mg tab po q 6h prn ___
5	650 mg tab po q 6h prn pain
6	650 mg tab po q 6h prn temperature > ___
7	Caplet (500 mg)
8	1000 mg caplet q 12h prn if fever or temperature ___
9	Suspension (160 mg/5 mL)
10	160 mg (5 mL) po q___h prn if temperature > 102
11	___ mg po q___h if temperature > 101
12	Drops (80 mg/0.8 mL)
13	80 mg (0.8 mL) po q4h prn if temperature ___
14	___ mg po q4h prn if temperature >102
15	Rectal

Look A-like, Sound A-like Medications

LOOK ALIKE, SOUND ALIKE MEDICATION

Sodium Bicarbonate Injection, USP is indicated in the treatment of metabolic acidosis. In infants (up to two years of age), the 4.2% solution is recommended for intravenous administration at a dose not to exceed 8 mEq/kg/day. Rapid infusion of bicarbonate and overcorrection of the metabolic acidosis (e.g., miscalculating dose or using higher concentration 8.4% in error) can lead to complications such as tetany, seizures, and hypokalemia by worsening the preexisting hypocalcemia and hypokalemia. Therefore, these two products are not to be interchanged.



TO PREVENT LOOK ALIKE, SOUND ALIKE MEDICATION ERRORS:

- Separate locations of look alike medications.
- Use look alike sound alike (LASA) auxiliary stickers on bins containing the medication
- Train staff to recognize LASA errors
- For handwritten/oral prescriptions, do not make assumptions; call the prescriber to confirm medication.
- Check patient's profile & review medication list to prevent errors

Safety Alert: Citalopram – New Maximum Daily Dose



The Food and Drug Administration (FDA) recently issued a drug safety communication stating that citalopram (Celexa®) **should no longer be used at doses greater than 40 mg per day due to the risk of QT interval prolongation.**

QT prolongation in some individuals can lead to torsade de pointes, a potentially life-threatening adverse event. The FDA has received post-marketing reports of torsade de pointes and significant QT prolongation at 60 mg citalopram.

Update for Healthcare Professionals

Highlights of the changes to the “Warnings” section of the package insert are listed below:

- 1-Citalopram causes dose-dependent QT prolongation and should not be dosed above 40 mg per day.
- 2-Citalopram should not be used in patients with congenital long QT syndrome.
- 3-Hypokalemia and hypomagnesemia should be corrected prior to initiation of treatment and periodically monitored.
- 4-ECG monitoring is recommended in patients with congestive heart failure, bradyarrhythmias, or patients on concomitant medications that prolong the QT interval.
- 5-Dose escalations over 20 mg in CYP2C19 poor metabolizers or in patients taking concomitant cimetidine or another CYP2C19 inhibitor are not recommended.

If these lower doses are not adequate, recommend switching to another antidepressant (sertraline, paroxetine, and fluoxetine seem less likely to cause QT prolongation)

For more information visit:

- 1-Food Drug Administration at <http://www.fda.gov/Drugs/DrugSafety/ucm269086.htm>
- 2-Celexa® (citalopram HBr) package insert: <http://www.frx.com/products/celexa.aspx>

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From The Harlem Hospital Pharmacy

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If you wish to contribute an article or commentary for Pharmacy Newsletter, contact H.Farooqi, Pharm.D. at hinnah.farooqi@nychhc.org no later than 15th of the month for the next issue.

Comparison Between Oral Anticoagulants



Oral anticoagulants prevent deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke work by reducing blood clotting. Oral agents include either dabigatran (Pradaxa) or warfarin (Coumadin).

When deciding to start or continue a patient on either dabigatran (Pradaxa) or warfarin (Coumadin), a patient focused approach as well as the drug's efficacy, side effects, monitoring, available antidotes and costs should be considered. Warfarin is on the Harlem Hospital Formulary, whereas dabigatran is currently non-formulary.

FDA labeled Indications:

- **Pradaxa** – A. Fib Treatment and prophylaxis.
- **Warfarin** – A. Fib Treatment and prophylaxis, PE and DVT treatment & prophylaxis. MI prophylaxis, Post MI thrombosis treatment and prophylaxis.

Efficacy – Studies show Pradaxa is more efficacious and 150 mg BID prevents 5 more strokes per 1000 patients/year than warfarin.

Side effects – Pradaxa has fewer Intracranial bleeds but more GI bleeds than Warfarin. Patients exhibit more dyspepsia with Pradaxa than Warfarin.

Monitoring – Warfarin requires frequent INR monitoring compared to no INR monitoring for Pradaxa. There are more drug and food interactions with Warfarin causing more concern than Pradaxa.

Cost – Cost is less with Warfarin (\$80/month). Pradaxa is more expensive (\$260/month).

Antidote – Available antidote for warfarin is Vitamin K. **However, Pradaxa has no antidote.**

Patient Counseling points –

- Continue suggesting Warfarin for many A. Fib patients unless interactions or monitoring is a problem.
- Pradaxa is now good for 4 months after opening instead of just 60 days.
- Recommend renal function monitoring and lower doses for the Pradaxa.
- Discourage using aspirin for A. Fib due to new evidence suggesting lack of benefit compared to placebo and an increased bleeding risk.

For more information visit:

<http://pharmacistsletter.therapeuticresearch.com/home.aspx?cs=&s=PL>

Pharmacy Employee of the Month



Pharmacy Interventions play a vital role in promoting patient safety. Interventions are a powerful medication safety strategy to prevent and reduce the risk of medication related errors from reaching the patient.

Harlem Hospital Pharmacy Medication Intervention Tracking and Trending system has been recognized as “Best Practice” by Regulatory Bodies such as The Joint Commission (TJC) as well as Harlem Hospital Administration.

We appreciate and expect all our pharmacists to continue making more interventions in order to improve patient care. During our Monthly Pharmacy Staff Meeting, Ms. Gayle Copeland was honored for constant communication with Health Care providers in order to promote safe and appropriate medication use.

We applaud her and encourage all the pharmacists’ to make interventions effectively in order to enhance patient safety.

XIGRIS

Withdrawn From the Market

Xigris (drotrecogin alfa [activated]), a recombinant form of human Activated Protein C was originally approved in 2001 for the treatment of severe sepsis. On October of 2011, Eli Lilly and company, announced to have all of its Xigris [drotrecogin alfa (activated)] products withdrawn from the market following the results of the PROWESS-SHOCK study. The study revealed a **lack of benefit** when treating severe septic shock. Moreover, the study results showed that the 28-day-all-cause mortality rate was actually **higher** in the patients who received Xigris compared to patients who received placebo

Based on these results, the following are FDA's suggestions to all healthcare professionals:

- Xigris treatment should not be started in new patients.
- Xigris treatment should be stopped in patients being treated with Xigris.
- All remaining Xigris product should be returned to the supplier from whom it was purchased.

For more information visit:

<http://www.medscape.com/viewarticle/752169>