

Take A Stand

Support Medication Safety



January 21, 2014

Important Notification Regarding Acetaminophen

The Food and Drug Administration (FDA) has taken action to improve safety for consumers who use the drug, acetaminophen. Overuse/abuse of acetaminophen has increased the incidence of severe liver injury, including liver failure. Watch *FDA: Don't Overdo it with Acetaminophen*: www.youtube.com/watch?v=hX7e3rrwyO8.

The FDA has limited the strength of acetaminophen in prescription products to 325 mg or lower. This change only applies to prescription drugs and does not apply to OTC medications. If a client/resident has an existing prescription for a drug containing more than 325 mg of acetaminophen you must:

- Contact the client/resident's healthcare provider immediately to discuss an appropriate replacement medication and to obtain a new prescription;
- Document any directions the healthcare practitioner gives regarding the existing prescription and/or OTC medications with the higher dose;
- Carefully monitor, document and report the client's/resident's pain management needs to their healthcare practitioner; AND
- **DO NOT** give the client/resident any OTC products that contain acetaminophen without obtaining a medical order.

NOTE: *There may be medical reasons your client/resident requires higher doses of acetaminophen. Generally, individuals requiring higher doses of any medication are carefully monitored. Keep all medical appointments and follow-up with all lab work ordered by the client's/resident's healthcare practitioner.*

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Although this change only applies to prescription drugs, the risk of liver injury or liver failure can occur when using OTC products containing acetaminophen.

Acetaminophen is an active ingredient found in many over-the-counter (OTC) and prescription medications. It is commonly used to relieve pain and reduce fever. It is often combined with other active ingredients to treat conditions associated with colds, flu, allergies and sleeplessness.

Additional FDA requirement changes to products containing acetaminophen:

- OTC products containing 500 mg of acetaminophen changed frequency from 4-6 hours to every 6 hours:
 - *If you continue to use existing OTC acetaminophen stock you must use the new frequency of every 6 hours for 500 mg of acetaminophen. Do not take more than six tablets/ capsules/ caplets in 24 hours, unless directed by a doctor.*
- Concentrated liquid formulas for infants and children will no longer be sold;
- The FDA also requires OTC products containing acetaminophen have the potential risks listed:
 - **“Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take • more than 4,000 mg of acetaminophen in 24 hours • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product.”
 - Warning for potential skin reactions, that can be life-threatening, when taking acetaminophen.

Many product names and terms are not standardized and can cause confusion. It is critical when purchasing any OTC product that you verify the active ingredients. The only way to determine what active ingredients you are purchasing is to carefully read the product label. See attached product label example.

Acetaminophen and other drug products that contain acetaminophen may use one of the following abbreviations: APAP, AC, Acetaminophn, Acetaminoph, Acetaminop, Acetamin or Acetam. **Do not use these abbreviations on the Medication Administration Record (MAR).**

If you still have questions or concerns contact the client's/resident's healthcare practitioner, nurse or nurse consultant or your local pharmacist.

Additional Information:

- Changes in frequency: www.tylenolprofessional.com/extra-strength-tylenol-dosage-instructions.html
- Liquid acetaminophen information: www.fda.gov/drugs/drugsafety/ucm284756.htm
- Potential skin reactions: www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm

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Drug Facts

Active ingredient (in each tablet)

Purpose

Acetaminophen 500 mg.....Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - the common cold
 - backache
 - minor pain of arthritis
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Do not use with any other drug containing acetaminophen (prescription or nonprescription).

If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have liver disease

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see Liver warning)

adults and children
12 years and over

- take 2 tablets every 6 hours while symptoms last
- do not take more than 6 tablets in 24 hours, unless directed by a doctor
- do not use for more than 10 days unless directed by a doctor

children under
12 years

ask a doctor

Other information store at 20°-25°C (68°-77°F)

Inactive ingredients carrageenan, corn starch*, croscarmellose sodium*, FD&C red #40 aluminum lake, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid, sucralose, talc, titanium dioxide
*contains one or more of these ingredients

Questions or comments? 1-888-██████████

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