HOT SPOT

Hang on Tight—Stories, Parables, Occurrences, Training

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FDA Launches Consumer Campaign on Safe Use of OTC Pain Products

January 22, 2004

The Food and Drug Administration (FDA) today launched a national education campaign to provide advice on the safe use of over-the-counter (OTC) pain relief products.

"Pain relievers and fever reducers are safe drugs when used as directed, but they can cause serious problems when used by people with certain conditions or those who are taking specific medicines," said FDA Commissioner Mark B. McClellan M.D., Ph.D. "We want to remind consumers who take these products that it's important to follow current dosing and label directions carefully."

FDA's nationwide campaign focuses on the OTC pain and fever reducers that contain acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs), which include products such as aspirin, ibuprofen, naproxen sodium and ketaprofen.

"'Read labels carefully, be sure you are getting the proper dose, and check with your doctor or pharmacist to be sure that you can use these drugs safely," said Dr. McClellan.

Many OTC medicines sold for different uses have the same active ingredient. For example, a cold-and-cough remedy may have the same active ingredient as a headache remedy or a prescription pain-reliever. To minimize the risks of an accidental overdose, consumers should avoid taking multiple medications that contain the same active ingredient at the same time.

Acetaminophen is an active ingredient found in more than 600 OTC and prescription medicines, such as pain relievers,

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MORTALITY ALERT!

Constipation

Thanks to Henry M.Taylor, MD for this informative article.

Almost everyone experiences constipation sometime in their lives. For most of us, the problem is transient and more troubling than dangerous. However, in extreme cases, constipation can be deadly, literally.

Normally, material is propelled through the colon by the coordinated contraction and relaxation of involuntary muscles in the wall of the colon, and these involuntary muscles are, in turn, controlled by a part of the nervous system called the autonomic nervous system. While material transits the colon, the colon generally absorbs water and electrolytes; also, the colon serves to store its contents until evacuation is convenient and socially appropriate. When the transit of material through the colon is slowed to the point when less than three bowel movements occur per week, this condition is called constipation. Actually, a more complete definition of constipation includes the presence of symptoms related to deficatory dysfunction.

CAUSES

A number of medical conditions are often associated with constipation, including hypothyroidism, diabetes, cerebral palsy, spinal cord injury, various syndromes causing mental

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The HOT SPOT can be found on the web site for the State of Tennessee. Find it easily at www.state.tn.us/mental/publicate.html

MORTALITY ALERT!

Constipation *from page 1*

retardation, irritable bowel syndrome, prior stimulant laxative overuse, and anal outlet obstruction. New onset constipation may be caused by colo-rectal cancer. Improper diet may be a contributing factor. In addition, a number of medications are known to cause or worsen constipation. Such medications include certain high blood pressure medications, certain pain medications, certain antacids, antihistamines, certain anti-seizure medications, certain medications used to treat mental illness, and calcium and iron supplements. The list is quite extensive. In some cases of constipation, there is an abnormality in the innervation and/or musculature of the GI tract, and there is the suggestion that these abnormalities are more common in people with developmental disabilities.

The spectrum of severity for constipation is quite broad. In its milder forms, it causes mild discomfort, perhaps leading to irritability which, in people with developmental disabilities, may manifest as self-injurious or aggressive behavior. In general, mild cases are easily relieved by relatively simple measures. However, in the most severe cases, constipation can cause great suffering and lead to very serious, life-threatening complications, such as aspiration pneumonia, intestinal perforation, and complete intestinal failure. Several medications and even surgery may be required to manage constipation in these very severe cases. In the extreme cases, sometimes referred to as intestinal pseudo-obstruction, there is almost complete cessation of movement of material through the colon, and all measures may fail to relieve the problem.

TREATMENT

In the less severe cases of constipation, simple measures should be instituted first. The diet should contain foods such as fruits and vegetables that provide adequate fiber content, or fiber supplements should be provided. In addition, adequate fluids should be provided, as even minimal dehydration can cause stools to be hard and, therefore, difficult to pass. For people who cannot freely access water for themselves, caregivers must be very aware of the importance of providing sufficient fluids. Finally, exercise should be encouraged, when possible, because exercise facilitates the movement of material through the colon. If exercise in not possible, positioning programs can offer some substitute benefit. If constipating medications can be discontinued, this should be done, but, unfortunately, this is not always possible.

If these measures don't provide relief, then laxative medications should be utilized or prescribed. Laxatives are frequently divided into the following categories: stool softeners, stimulants, and osmotic agents. The stool softeners are generally considered the mildest laxatives, and they are a good first choice. However, it is unlikely that they will be sufficient to treat severe cases. Stimulant laxatives are generally more effective, but their prolonged regular use has been linked to progressive constipation and lack of response to continued treatment. If stimulant laxatives are to be used, they are perhaps best used intermittently. Finally, osmotic agents, such as Lactulose and MiraLax, are generally safe and effective.

In addition to laxatives, a few new medications can be used to treat constipation by stimulating the autonomic nervous system that controls colonic activity.

For extremely severe cases of constipation, such as intestinal pseudo-obstruction, surgery is sometimes indicted, including partial or complete removal of the colon. Another therapeutic approach that is sometimes utilized is total parenteral nutrition (TPN), thus altogether bypassing the GI tract in the delivery of nutrients.

It is often difficult to decide just how aggressive one should be in the treatment of constipation, especially since one often hears criticism about the overuse of laxatives. To help with this decision, one should keep the goals of treatment in mind. These goals should be the relief of discomfort, the production of a bowel movement at least three times per week, and the prevention of abdominal distension, a possible sign of the development of serious problems. Treatment should be advanced until these goals are achieved. In this way, hopefully, the constipation will not progress and the potentially very dangerous complications avoided.

MedWatch

The FDA Safety Information and Adverse Event Reporting Program

Ortho-McNeil and FDA revised the WARNINGS and PRECAUTIONS sections of the prescribing information, notifying healthcare professionals that **Topamax** causes hyperchloremic, non-anion gap metabolic acidosis (decreased serum bicarbonate). Measurement of baseline and periodic serum bicarbonate during Topiramate treatment is recommended.

MORTALITY ALERT!

Observation tools for direct care staff

Direct care staff have more direct daily contact with an individual than any other members providing care. As a caregiver, you may save an individual's life or prevent complications of illness or injury by noticing and reporting problems correctly. Following agency policy and procedures for reporting is vital. When a person has a plan of care, following that plan is crucial. Flow sheets used for observations must be presented to direct care staff along with a complete explanation of their use and importance. Direct care staff have a responsibility to insist that someone be made aware of observations and provide interpretation.

The following are some problems that should be noticed and reported.

- Shortness of breath. If person becomes short of breath assist to comfortable position in bed with head elevated, or in chair, and notify someone immediately.
- Very fast breathing or very slow breathing or any significant change in person's usual rate and depth of breathing. If rate is extremely high or low, of if change is extreme or sudden, notify someone immediately.
- Fever. If skin feels very hot or dry or looks flushed, ask if temperature should be taken. Notify someone as policy indicates. Dehydration can occur quickly and pose danger to the person.
- Cough. Notice if cough is hoarse or dry. Notice and report immediately if person coughs so hard as to become short of breath. Notice what triggered the cough, such as difficulty swallowing. Notice color, quantity, odor and any other substances such as blood in any sputum coughed up by the person. Report bloody sputum immediately.
- Chills. Report if person shivers or complains of feeling cold in a warm room and/or when warmly dressed.
- Chest pain. If person is in obvious severe distress, call 911 immediately. Do not wait.
- Nausea/vomiting. Notify someone as soon as possible according to agency policy. Dehydration can occur quickly and pose danger to the person. If the person vomits black substance (like coffee grounds), or bright red blood, call 911 immediately. Do not wait.
- Excessive thirst. Report persistent extreme thirst as it may indicate dehydration, diabetes, or a number of internal problems. Notice if exertion or a hot room might be part of the cause.
- Skin color (check oral mucosa, sclera, and/or nail beds for color). Report all of the following. Cyanosis or blue tinge. Pallor or pale color. Reddened areas on the surface of skin may be rash, allergy, or start of decubitus ulcer. Flushed, red, or pink color skin may be a sign of fever, sun exposure, or wound inflammation. Yellow skin may be caused by excessive intake of carotene or may be jaundice, which is a sign of a liver problem. Purple, blotchy patches or mottling on lower extremities may be a sign of poor circulation or that a person is too cold. Other skin problems to report include wounds, bruises, cracks, dry patches, rashes, open areas, and skin tears. Give special attention to any new warts or moles, or any changes in old ones.
- Pus or drainage from a wound or from any body opening may be a sign of infection.
- Urine sediment, color, odor, frequency, burning.
- Pain. Report any sign of pain that is sudden or severe (especially chest or abdominal pain) immediately.
- Report any change in normal level of consciousness, report sudden or extreme change immediately. Call 911 immediately if stroke or heart attack is suspected.
- Report any change from person's usual behavior. Report any sudden or extreme changes immediately. Behavioral changes often indicate a physical problem, e.g. dehydration.
- Dehydration. Severe or prolonged dehydration can be life threatening; report symptoms before it gets this serious. Look for such things as dry cracked lips, increased constant thirst, lack of urine or highly concentrated urine, etc.
- Edema. Report any sudden or large weight gain and any swelling on the body.
- Changes in appetite or eating habits can be due to illness, heat, unpleasant atmosphere, emotional distress, food preferences, or any number of other reasons. Report unusual weight gain or loss that occurs quickly and for no reason.
- Report any changes in bowel elimination. Report complaints of pain, itching, or burning when having a bowel movement. Report active bleeding immediately.
- Bleeding. Report any bleeding from wounds or body openings. In case of a cut or injury with heavy bleeding, apply pressure using universal precautions and obtain assistance immediately. Vomiting blood requires immediate notification and/or 911 assistance.

Any changes in what is usual and normal for each person can mean a change in their medical/mental condition. Observe and report any changes per policy, procedure, and/or plan of care.

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cough suppressants and cold medications. It is safe and effective when used correctly, but taking too much can lead to liver damage, and even death. The risk for liver damage may be increased in consumers who drink three or more alcoholic beverages per day while using acetaminophen-containing medicines.

NSAIDs are common pain relievers that are also used to relieve fever and minor aches and pains. Examples of NSAIDs are aspirin, ibuprofen, naproxen sodium, and ketaprofen. These products can cause stomach bleeding with an increased risk in consumers who are over 60, are taking prescription blood thinners, are taking steroids or have a history of stomach bleeding. NSAIDS may also increase the risk of reversible kidney problems in consumers with preexisting kidney disease, or who are taking a diuretic (water pill).

In September 2002, FDA's Non-Prescription Drug Advisory Committee recommended changes to labeling of certain OTC drug products, including acetaminophen and NSAIDS. They advised that these changes are needed to better inform consumers about the ingredients in these products and possible side effects caused by improper use. In addition to this new consumer outreach effort, FDA will consider changing the labeling of these products to further bolster their safe use. FDA is reviewing various changes to labeling for these ingredients that better reflect the latest scientific knowledge about OTC oral pain relievers.

The FDA recommends that consumers talk with healthcare professionals or pharmacists if they have questions about using an OTC medicine and especially before using them in combination with dietary supplements or OTC or prescription medicines. To learn more, call 1-888-INFO-FDA or visit www.fda.gov/cder.

Pursuant to the State of Tennessee's policy of nondiscrimination, the Department of Mental Health and Developmental Disabilities does not discriminate on the basis of race, sex, religion, color, national or ethnic origin, age, disability, or military services in its policies, or in the admission or access to, or treatment or employment in, its programs, services or activities.

The Tennessee Department of Mental Health and Developmental Disabilities is committed to principles of equal opportunity, equal access and affirmative action. Contact the department's EEO/AA Coordinator at (615) 532-6580, the Title VI Coordinator at (615) 532-6700 or the ADA Coordinator at (615) 532-6700 for inquiries, complaints or further information. Persons with hearing impairment should call (615) 532-6612.

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