AU InforMed

Volume 6 Number 12 (Issue 189)

Wednesday, April 30, 2008

Guest Editors: Joseph Madsen, PharmD Candidate; Eston Cobb, PharmD Candidate; Wesley Lindsey, PharmD

Key Inforbits

- FDA investigates possible link between Singulair use and suicide
- 10 Quick tips for Patients with Asthma
- Relationship between Asthma and GERD
- Overview of Exercise-Induced Asthma
- Do you know someone with Asthma?
- Interesting Facts about Asthma



May is... Asthma Awareness Month



FDA Investigates Possible Increased Risk of Suicide Among Singulair Users



On March 27, 2008 the FDA released an early communication about an ongoing safety review of montelukast (Singulair). They are investigating a possible association between the use of Singular and behavioral/mood changes, suicidality (suicidal thinking and behavior), and suicide. This after the drug manufacturer, Merck, released data from post marketing adverse event reports of depression, anxiety, and suicidality.¹

At this point it is not clear if there is a relationship between the drug and an increased risk of suicide and full information may not be available before the end of the year. Patients are advised that they should not stop taking Singulair without first talking to their doctors. Healthcare professionals are advised to monitor patients taking Singulair for suicidality and changes in behavior and mood. Package labeling has been updated to reflect this possibility (<u>http://www.singulair.com/montelukast_sodium/singulair/consumer/index.jsp</u>).

Singulair is a medicine in the class of drugs known as the leukotriene receptor antagonists. Singulair is used to treat asthma, the symptoms of allergic rhinitis (sneezing, nasal congestion, runny nose), and to prevent exercise-induced asthma. The FDA is also reviewing post-marketing reports of other leukotriene modifying medications including Accolate, Zyflo, and Zyflo CR.

The FDA urges both healthcare professionals and patients to report side effects from the use of Singulair, Accolate, Zyflo, and Zyflo CR to the FDA's MedWatch Adverse Event Reporting program online at <u>www.fda.gov/medwatch/report.htm</u> or by telephone at 1-800-332-1088. 1. Early communication about an ongoing safety review of montelukast (Singular). [homepage on the internet] Rockville, MD: Food and Drug Administration Center for Drug Evaluation and Research. Created on March 27, 2008; cited April 24, 2008. Available from: http://www.fda.gov/Cder/drug/early_comm/montelukast.htm.

10 Quick Tips for Patients with Asthma

- 1. Keep an allergy diary: Knowing what causes your asthma attacks can help you to avoid those triggers in the future.
- 2. Say goodnight to dust mites: Cover pillows and mattresses with allergen-proof zippered covers and wash all bedding in hot water at least once a week.
- **3.** Regularly change air filters on heaters and air conditioners.
- **4.** Keep pets outdoors if possible: Pet dander, hair, and saliva can trigger outbreaks.
- 5. Keep it high and dry: Use a dehumidifier to prevent the growth of mold in damp areas like the bathroom or kitchen.
- **6.** Avoid clutter: Too much clutter in your home is a haven for dust and allergens.
- 7. Dust with a damp cloth and vacuum regularly to prevent the accumulation of allergens in your home, and be sure to wear a mask.



- **8.** Stop bugging me: Household pests like cockroaches can also worsen allergy symptoms. Use insect baits or traps rather than sprays to eliminate them from your home.
- 9. Avoid secondhand smoke whenever possible.
- **10.** Use a peak flow meter to detect when your asthma is worsening and have a management plan in place.

1. WebMD. Controlling asthma triggers. The WebMD Staff. Updated 2008 Mar 13. Accessed 2008 Apr 23. Available from: http://www.webmd.com/asthma/asthma-symptoms-7/asthma-triggers.

2. United States Environmental Protection Agency. Clearing the air of asthma triggers. Indoor Environments Division. Updated 2004 May. Accessed 2008 Apr 23. Available from: <u>http://epa.gov/asthma/pdfs/10_steps_en.pdf</u>.

FROM THE MEDICAL LITERATURE

Relationship between Asthma and GERD



A recent meta-analysis by Havemann et al. examined the available literature on the relationship between asthma and gastroesophageal reflux disease (GERD). The researchers found that the average prevalence of reflux symptoms in adults with asthma was 59% compared to an incidence of 10-20% in the general population. In addition, the frequency of GERD symptoms appears to increase along with severity of asthma.¹

There are two primary theories regarding the cause and effect relationship between asthma and GERD. The reflux theory states that acid reflux causes damage to the throat, airways, and lungs which leads to asthma-like symptoms in patients with GERD. Alternatively, in the reflex theory, the

presence of acid in the esophagus causes stimulation of the vagal nerve. This leads to vasoconstriction of the airways to prevent the acid from entering.¹

In patients with both GERD and asthma it is important to maintain control of asthma symptoms to minimize exacerbations of acid reflux symptoms and vice versa. Littner et al. studied the effects of PPI therapy on asthma control in patients with both asthma and acid reflux symptoms. There was a significant reduction in the number of asthma exacerbations in the group receiving PPI therapy compared to the placebo group (odds ratio was 2.9). There was also a reduction in the severity of asthma exacerbations in patients on PPIs.²

2. MR Littner, FW Leung, ED Ballard, B Huang, NK Samra. Effects of 24 weeks of lansoprazole therapy on asthma symptoms, exacerbations, quality of life, and pulmonary function in adult asthmatic patients with acid reflux symptoms. Chest. 2005;128(3):1128-35.

^{1.} Havemann BD, Henderson CA, El-Serag HB. The association between gastro-oesophageal reflux disease and asthma: a systematic review. Gut. 2007 Dec;56(12):1654-64.

Exercise-Induced Asthma

Exercise-induced asthma (EIA) is defined as a condition in which exercise induces symptoms of asthma in patients who have asthma. The pathogenesis is not fully understood but is believed to be caused by exercise-induced hyperventilation and a corresponding change in airway physiology. Vigorous exercise results in increased amounts of cold and dry air, causing a loss of mucosal heat, which induces changes in the airway surface and leads to the activation of mast cells and the release of pro-inflammatory mediators like histamine, leukotrienes, and chemokines.



The prevalence of EIA varies from 5-20% in the general population, up to 30-70% in elite winter athletes and athletes who participate in summer endurance sports. The increase is believed to occur because of increased exposure to particular environmental asthmogenic agents, polluted air, cold and dry air, and exercise involving high ventilation rates.

Typical symptoms of EIA are cough, wheezing, chest tightness, and unusual shortness of breath occurring after a burst (6-8 minutes) of strenuous and continuous exercise. Non-specific symptoms include poor performance, abdominal pain, headaches, muscle cramps, fatigue, dizziness, seasonal change in fitness, sore throat in young children, worsening problems associated with triggers, prolonged difficulty eliminating upper respiratory illness (locker room cough). Due to the unacceptable false positive and false negative rates, diagnosis based on self reported symptoms is not recommended. This is especially true with elite athletes due to the potential for asthma treatments to be abused in order to obtain a competitive edge by increasing their oxygen intake capacity.

The most direct method of diagnosis is to perform an exercise challenge. The goal is to achieve 40-60% of maximum voluntary ventilation for no more than 6-8 minutes of exercise in an environment of controlled humidity and temperature. Forced expiratory volume in one second (FEV₁) is measured before and at regular intervals throughout the challenge. EIA is defined by a 10% drop of FEV₁ from baseline under the above conditions.

Treatment of EIA focuses on pre-medication and warm-up. A 10-15 minute warm-up that includes calisthenics combined with stretching to reach a target of 50%-60% of maximum heart rate may be helpful in preventing EIA. Mast cell stabilizers or short-acting β -agonists may also be taken prophylactically 15 minutes before exercise. In addition, breathing through the nose may decrease EIA by allowing the cool, dry air to be humidified and warmed before entering the lungs. A cool-down period of mild physical activity lasting 10-15 minutes may prevent rapid rewarming that can also lead to airway obstruction.

1. Weiler J, Bonnini S, Coifman R, Craig T, et al. American Academy of Allergy, Asthma & Immunology work group report: Exercise-induced Asthma. J Allergy Clin Immunol. 2007;119:1349-58.



DO YOU KNOW SOMEONE WITH ASTHMA?

Below are some well-known people who have been diagnosed with asthma.

- John F. Kennedy, 35th President of the United States
- Jackie Joyner-Kersee, three-time Olympic gold-winning track-and-field athlete
- Ludwig van Beethoven, composer
- Charles Dickens, novelist
- Christopher Reeve, actor who played Superman
- Nancy Hogshead, three-time Olympic gold-winning swimmer
- Dennis Rodman, former NBA star
- Jason Alexander, actor who played George on *Seinfeld*
- Peter the Great, 18th century Russian Czar
- Elizabeth Taylor, actress
- Bob Hope, entertainer

For more information, please see: <u>http://www.teenasthma.ca/celebswithasthma.jsp</u> or



http://www.healthsmart.org/ibreathe/2 0 asthma/2 2 6 famous people.htm

QUICK FACTS ABOUT ASTHMA

Did you know that....?

- 22 million Americans, including 6.5 million children have asthma
- There is a higher incidence of asthma in people of low socioeconomic status
- Asthma accounts for nearly 15 million physician visits, and 2 million emergency department visits each year
- Rates of asthma-related emergency department visits, hospitalizations, and deaths are higher in African Americans than Caucasians
- Total annual costs due to asthma are estimated at \$16 billion
- Asthma is the most common serious chronic disease of childhood
- 1 in 13 school-aged children has asthma
- One-third of all pediatric emergency department visits are due to asthma

For more information, go to http://www.cdc.gov/asthma/

The Last Dose

" It is the mark of an educated mind to be able to entertain a thought without accepting it." ~Aristotle [384 - 322 B.C.]

 An electronic bulletin of drug and health-related news highlights, a service of ... Auburn University, Harrison School of Pharmacy, Drug Information Center
Phone 334-844-4400 • Fax 334-844-8366 • <u>http://www.pharmacy.auburn.edu/dilrc/dilrc.htm</u> Bernie R. Olin, Pharm.D., Director