

SPRING 2007

PD MEDICATION ALERT: FDA PUBLIC HEALTH ADVISORY PEROGLIDE (MARKETED AS PERMAX)

The FDA is notifying you that the companies that manufacture and distribute pergolide have agreed to withdraw this drug from the market due to the potential for heart valve damage. Two new studies showed that patients with Parkinson's disease who were treated with pergolide had an increased chance of serious damage to their heart valves when compared to patients who did not receive the drug. Pergolide is a member of a class of drugs known as dopamine agonists and is used with levodopa and carbidopa to manage the signs and symptoms (tremors and slowness of movement) of Parkinson's disease.

PATIENTS WITH PARKINSON'S DISEASE WHO ARE TAKING PERGOLIDE SHOULD:

- Contact their healthcare professional to discuss alternate treatment options.
- NOT stop taking Pergolide without consulting their healthcare professional, since stopping pergolide too quickly can be dangerous and several other effective treatments are available.

HEALTHCARE PROFESSIONALS WHO PRESCRIBE PERGOLIDE SHOULD CONSIDER THE FOLLOWING:

- Assess the patient's need for dopamine agonist (DA) therapy. If continued treatment with a DA is necessary, another DA should be substituted for pergolide. There are other dopamine agonists approved for the treatment of Parkinson's disease that are not associated with heart valve damage. Published transition regimens describe the conversion from one DA to another.
- If treatment with a DA is to be discontinued, pergolide should not be stopped abruptly, because rapid discontinuation of all dopamine agonist therapies can be dangerous. Instead, gradually decrease the dose of pergolide.
- Patients who will be taken off pergolide should be told that other effective options for treatment exist, including three other DAs that are not associated with damage to heart valves.

In 2006, a boxed warning regarding the risk of serious heart valve damage was added to the labeling for pergolide. The two recent studies, published in *The New England Journal of Medicine* in January 2007, confirm earlier studies that also described this problem. Pergolide is marketed by Valeant under the trade name Permax and sold and manufactured as the generic drug pergolide by Par and Teva.

In light of this additional safety information and the availability of alternative treatments for Parkinson's disease that do not have comparable safety problems, the companies that manufacture and sell pergolide have stopped shipping pergolide for distribution and will, in cooperation with FDA, work to remove from the market both the name brand Permax. (pergolide) and the generic versions of pergolide. The effect of this voluntary withdrawal on supplies of pergolide currently in pharmacies will not be immediate. This delay will allow time for healthcare professionals and patients to discuss appropriate treatment options and to change treatments.

One of the drugs that was included in the recent studies showing increased chance of heart valve problems is Dostinex (cabergoline), another dopamine agonist. This drug is approved in the U.S. for the treatment of hyperprolactinemic disorders (conditions in which there are elevated levels of prolactin in the blood). Dostinex is not approved in the U.S. for the treatment of Parkinson's disease. For hyperprolactinemic disorders, a considerably lower dose of Dostinex is used. At these lower doses of Dostinex, there appears to be little chance of heart problems; therefore, Dostinex will remain on the US market for the treatment of hyperprolactinemic disorders.

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HUMOR

How to stay young:
Throw out nonessential
numbers. This includes age,
weight and height. Let the
doctors worry about them.

CLINICAL TRIALS

If you are interested in
participating in or would
like to learn more about
clinical trials for Parkinson's
Disease, please contact
Robyn Gibbs at 303-783-4974.

COMMENTS OR IDEAS FOR FUTURE ARTICLES IN THIS NEWSLETTER

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MOTOR COMPLICATIONS OF PARKINSON'S DISEASE

Motor complications of Parkinson's disease may include motor fluctuations, dyskinesias, off-period dystonia and freezing episodes. Many people with PD have several years of smooth control of their symptoms without complications. The thought is that the remaining neurons in the substantia nigra are still sufficiently active to smooth out fluctuations in the concentration of levodopa to provide a steady level of dopamine. As the disease progresses, more neurons are lost, thus causing the inability for the brain to "regulate" dopamine levels and subsequently causing the development of motor fluctuations.

Not everyone will experience motor complications, however, up to 40% of patients may experience these symptoms after 5-7 years of levodopa therapy.

MOTOR FLUCTUATIONS (LEVODOPA "ON/OFF" PHENOMENON):

- Refers to the abrupt and often unpredictable changes in motor state.
- "ON" is the period when medication is providing symptomatic relief with regard to mobility, bradykinesia (slow movements) and rigidity.
- "OFF" is the period when symptomatic benefits have been lost.

- Some advanced PD patients may experience a sudden switch to the "OFF" state or "dose" failure.

Motor fluctuations may be treated by adjusting the anti-parkinson medications. The physician may alter timing and dosages of current medications or may consider adding medications such as dopamine agonists (Requip or Mirapex), COMT inhibitor (Comtan), MAO-b inhibitors (selegiline, rasagiline) or apomorphine. The idea of this type of management is to extend the timing between doses without increasing the amount of levodopa.

DYSKINESIA

- Abnormal, involuntary, writhing type movements; the person may look as if they are wiggly, jerky and/or twisting.
- Generally occurs during the peak effect of a dose of levodopa.
- Rarely occur when medications are wearing off.

Dyskinesias may be decreased by reducing the amount of levodopa at each dose and increasing the frequency of doses and/or adding a dopamine agonist, COMT inhibitor or MAO-B inhibitor (eldepryl, azilect). Amantadine may also help with decreasing dyskinesias.

PD MEDICATION ALERT (CONTINUED FROM FRONT)

The FDA is working with the manufacturers of pergolide to determine if it is possible to make the drug available to those few patients who are currently taking pergolide where previous efforts to switch to a different treatment have been unsuccessful, or where efforts subsequent to this advisory

to switch therapies are also unsuccessful. In the interim, healthcare professionals and patients should consider all treatment options with the understanding that in the future, the drug may no longer be available.

NEWS

Dr. Pinky Agarwal is moving out of state with her family in April 2007. We wish Dr. Agarwal the best and would like to thank her for all of the work and help that she has provided for the Movement Disorders Community in Colorado. Good Luck Pinky! We will miss you!

SUPPORT GROUPS

We are fortunate in Colorado to have the Parkinson Association of the Rockies (PAR). PAR is a wonderful non-profit organization that has a great PD library plus has over 30 PD support groups in Colorado, Western Nebraska and Wyoming. Support groups allow patients and families to network with others who have the same disease and to share coping strategies with the physical, social and psychological challenges that are faced on a daily basis.

**You may contact PAR at: 303-830-1839 or
check their web: www.parkinsonrockies.org**

PD SYMPOSIUM

EDUCATION FOR PARKINSONIANS, FAMILY & CAREGIVERS

Saturday, May 19th, 2007
8:30 AM - 12:00 Noon

Colorado Springs Senior Center
1514 N. Hancock Avenue
Colorado Springs, CO

Presented by the Colorado Parkinson Foundation
And the Jeanne Taylor Parkinson's Support Group
of Colorado Springs.

**For more information, contact: 719-884-0103
or www.co-parkinson.org**