

# FDA Announces Voluntary Withdrawal of Pergolide Products<sup>1</sup>

## Help Patients Continue on Therapy—Consider REQUIP (a non-ergot dopamine agonist) for Parkinson's Disease

Pergolide products have been voluntarily pulled from the market, leaving many patients in need of new treatment. These patients may need alternative dopamine agonist therapy to manage their symptoms of Parkinson's disease. As always, patients are advised to talk to their healthcare professional before starting or stopping treatment. Consider REQUIP, a dopamine agonist indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease, for both early and advanced Parkinson's disease.

- REQUIP is the most prescribed dopamine agonist\*
- REQUIP has an established safety and tolerability profile
- REQUIP has been used in clinical practice in the US since 1997
- REQUIP offers progressive dosing to meet individual patient needs

**REQUIP enabled close to a 2-hour daily reduction in awake time spent "off" in a 6-month adjunct therapy trial<sup>2†</sup>**

**AAN guidelines identify REQUIP as an effective option for reducing "off" time<sup>3</sup>**

GlaxoSmithKline offers the Patient Savings Program for REQUIP, an opportunity for eligible patients to save up to \$15 on their next 7 filled prescriptions. Patient not enrolled? Talk to your GlaxoSmithKline Representative or call 1-888-825-5249.

If you have questions concerning how to dose REQUIP, please see the accompanying Prescribing Information, contact your local GlaxoSmithKline Representative, or call the GSK Response Center at 1-888-825-5249.

### Important Safety Information

REQUIP has been associated with sedating effects, including somnolence, and the possibility of falling asleep while engaged in activities of daily living, including operation of a motor vehicle. REQUIP should be discontinued if these events occur; it is unknown if dose reduction will eliminate episodes of somnolence. Prescribers should reassess patients for somnolence throughout treatment.

Syncope or symptomatic hypotension may occur, particularly during initial treatment or dose titration. Patients should be cautioned against rising rapidly after sitting or lying down. Because of possible additive effects, caution should be exercised with patients who have sleep disorders or are taking sedating medications, alcohol, CNS depressants, or medications that increase ropinirole plasma levels.

Hallucinations may occur at any time during treatment. REQUIP may potentiate the dopaminergic side effects of L-dopa and may cause and/or exacerbate pre-existing dyskinesias.

Patients and caregivers should be informed that impulse control symptoms, including compulsive behaviors such as pathological gambling and hypersexuality, have been reported in patients treated with dopaminergic agents, including ropinirole. These behaviors were reported principally in Parkinson's disease patients treated with dopaminergic agents, especially at higher doses.

\*Verispin's Vector One<sup>®</sup>: National, Verispin, L.L.C. Based on total U.S. retail prescriptions dispensed for Dopamine Agonists during the twelve months ending June 2006.

<sup>†</sup>Data from a 6-month, double-blind, multicenter, randomized, placebo-controlled trial of REQUIP as adjunct therapy with supplemental L-dopa in patients with PD (Hoehn & Yahr stage II-IV at baseline). The primary end point was a  $\geq 20\%$  reduction in awake time spent "off" and a  $\geq 20\%$  reduction in total daily L-dopa dose between baseline and final visits.

<sup>‡</sup>Analysis of the change in total awake hours spent "off" over 2 days. Mean change from baseline for REQUIP (-3.72) vs placebo (-1.86). An analysis for 1 day was calculated as  $-3.72/2 = -1.86$  for REQUIP and  $-1.56/2 = -0.78$  for placebo. Analysis for 1 week calculated as  $1.86 \times 7$  (13.02) and  $0.78 \times 7$  (5.45), respectively.

**References:** 1. Department of Health and Human Services. "FDA Public Health Advisory." March 29, 2007. Available at: <http://www.fda.gov/cder/drug/advisory/pergolide.htm>. Accessed April 13, 2007. 2. Data on file, GlaxoSmithKline. 3. Pahwa R et al. *Neurology*. 2006;66:983-995.

Please consult accompanying complete Prescribing Information.



**REQUIP<sup>®</sup>**  
ropinirole HCl

A Progressive Therapy  
for a Progressive Disease  
[www.requip.com/pd](http://www.requip.com/pd)