

November 2010

Dear Healthcare Professional:

The purpose of this letter is to inform you of important safety information for PROVIGIL[®] (modafinil) Tablets [C-IV] and important new safety information for NUVIGIL[®] (armodafinil) Tablets [C-IV].

Post-marketing cases of serious rash have been reported in adults taking NUVIGIL. Accordingly, Cephalon has updated the language in the NUVIGIL product labeling to incorporate this new safety information in the bolded **WARNING** regarding Serious Rash.

In addition, Cephalon has developed a Risk Evaluation and Mitigation Strategy (REMS):

- To inform healthcare providers about the risk of serious skin rash and other hypersensitivity reactions, particularly in pediatric patients, treated with PROVIGIL or NUVIGIL.
- To inform patients about the serious risks associated with PROVIGIL and NUVIGIL therapy.

Important Risk Information:

PROVIGIL and NUVIGIL increase the risk of serious rash, including Stevens-Johnson Syndrome, and other hypersensitivity reactions. These risks, which are described in the **WARNINGS** section of the PROVIGIL and NUVIGIL Prescribing Information, are delineated below:

Serious rash, including Stevens-Johnson Syndrome and other hypersensitivity reactions

Serious rash and other hypersensitivity reactions requiring hospitalization and discontinuation of treatment have been reported in adults in association with the use of modafinil and armodafinil and in children in association with the use of modafinil. Because armodafinil is the R isomer of racemic modafinil, a similar risk of multi-organ hypersensitivity reactions and serious rash in pediatric patients with NUVIGIL cannot be ruled out.

PROVIGIL and NUVIGIL should ordinarily be discontinued at the first sign of rash, unless the rash is clearly not drug-related. Discontinuation of treatment may not prevent a rash from becoming life-threatening or permanently disabling or disfiguring. PROVIGIL and NUVIGIL should also be discontinued in the event of any signs or symptoms suggestive of a multi-organ hypersensitivity reaction, angioedema, or anaphylaxis (e.g., swelling of the face, eyes, lips, tongue or larynx; difficulty in swallowing or breathing; hoarseness).

Data from clinical trials with modafinil suggest that the risk of serious skin reactions may be higher in the pediatric population. **PROVIGIL and NUVIGIL are not approved for use in pediatric patients for any indication.**

Please also note the following important risk information for NUVIGIL:

Please be aware of similarities between the trade name NUVIGIL and Norinyl (norethindrone and ethinyl estradiol tablets, USP). Ensure that prescriptions for NUVIGIL are clearly written and report any actual or potential medication errors involving NUVIGIL and Norinyl to Cephalon's Medical Services Department at 1-800-896-5855.

Enclosed for your review please find the full prescribing information for PROVIGIL and NUVIGIL, which contains other important safety information. At the end of the prescribing information is a copy of the Medication Guide that patients will receive from the pharmacy each time that they receive PROVIGIL or NUVIGIL. They should be instructed to read the Medication Guide before they start taking PROVIGIL or NUVIGIL and each time that they get a refill.

Information regarding the REMS may be obtained online at www.nuvigilrems.com or www.provigilrems.com.

To report adverse patient experiences or request further information on PROVIGIL or NUVIGIL, please contact Cephalon's Medical Services Department at 1-800-896-5855. Alternatively, adverse events may be reported to the FDA's MedWatch reporting system:

- by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178),
- online (<https://www.accessdata.fda.gov/scripts/medwatch>) or
- mailed, using MedWatch for FDA 3500 postage paid form, to the FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787

Cephalon is committed to providing healthcare professionals with useful information to guide the safe and appropriate use of its medicines. Thank you for your attention to this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Robert Kaper, MD'. The signature is written in a cursive style with a prominent initial 'R' and a long horizontal stroke extending to the right.

Robert Kaper, MD
Vice President
Medical Affairs

Enclosure: Full Prescribing Information for NUVIGIL
Full Prescribing Information for PROVIGIL