Cephalon
INSIGHTS INTO MEDICINE

03 February 2011

Direct Healthcare Professional Communication on restriction of indications for Modafinil (Provigil® 100 and 200mg tablets)

Dear Healthcare Professional

Summary

We would like to inform healthcare professionals that modafinil is now indicated **only** for the treatment of

- **adults with excessive sleepiness in patients with narcolepsy**, with and without cataplexy.

A review by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefit/risk profile of modafinil **is no longer favourable** for the treatment of excessive sleepiness associated with obstructive sleep apnoea (OSA), moderate to severe shift work sleep disorder (SWSD) and idiopathic hypersomnia.

Therefore, the indications to be deleted in Ireland, according to the currently licensed indications, are the treatment of:

- excessive sleepiness associated with chronic pathological conditions
- obstructive sleep apnoea/hypopnoea syndrome (OSAHS)
- moderate to severe chronic shift work sleep disorder (SWSD).

While this new advice does not require any urgent change in treatment, patients should have their treatment reviewed at the next routine appointment.

Further information

This review took account of the available information of the efficacy of modafinil in these indications and all safety concerns, including psychiatric and serious skin reactions, and the potential for cardiovascular adverse effects. The safety concerns associated with modafinil use were considered to outweigh the limited benefits of modafinil in OSA, SWSD and idiopathic hypersomnia. However, the benefit-risk balance of modafinil was considered to be positive in patients with narcolepsy.

As a result of this review, to support safer use of modafinil in narcolepsy CHMP has also concluded that:

- modafinil should not be used in the following groups:
  - patients with uncontrolled hypertension or cardiac arrhythmias
  - children
  - pregnant or lactating women

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- modafinil should be discontinued and not restarted in cases of:
  - serious skin or hypersensitivity type reactions
  - psychiatric disorders such as suicidal ideation
- a baseline ECG should be performed before modafinil treatment is initiated
- cardiovascular function, especially blood pressure and heart rate, should be regularly monitored
- the recommended starting daily dose is 200mg

Furthermore, modafinil should be used with caution in patients with a history of:

- psychosis, depression or mania
- alcohol, drug or illicit substance abuse

Such patients should be closely monitored and advised to report any suspected adverse behaviours or thoughts, to facilitate immediate evaluation and treatment discontinuation, if warranted.

Patients should be advised to contact their doctor if they are unsure as to whether they should discontinue modafinil treatment or not.

While there is no need for patients to stop treatment with modafinil immediately, patients who wish to stop can do so at any time.

For further information, please refer to the attached Summary of the Product Characteristics.

Reporting of suspected adverse drug reactions

Healthcare professionals should report any adverse events suspected to be associated with the use of Provigil to Cephalon Medical Information by phone on 1800 535 669, or by email at: UKMedInfo@cephalon.com.

Any suspected adverse reaction may also be submitted directly to the Irish Medicines Board (IMB) via www.imb.ie or by using the Yellow Card reporting system.

For further information or any questions on Provigil please do not hesitate contacting Cephalon Medical Information by phone on 1800 535 669, or email at UKMedInfo@cephalon.com.

Yours faithfully

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