

Provigil advertisement.

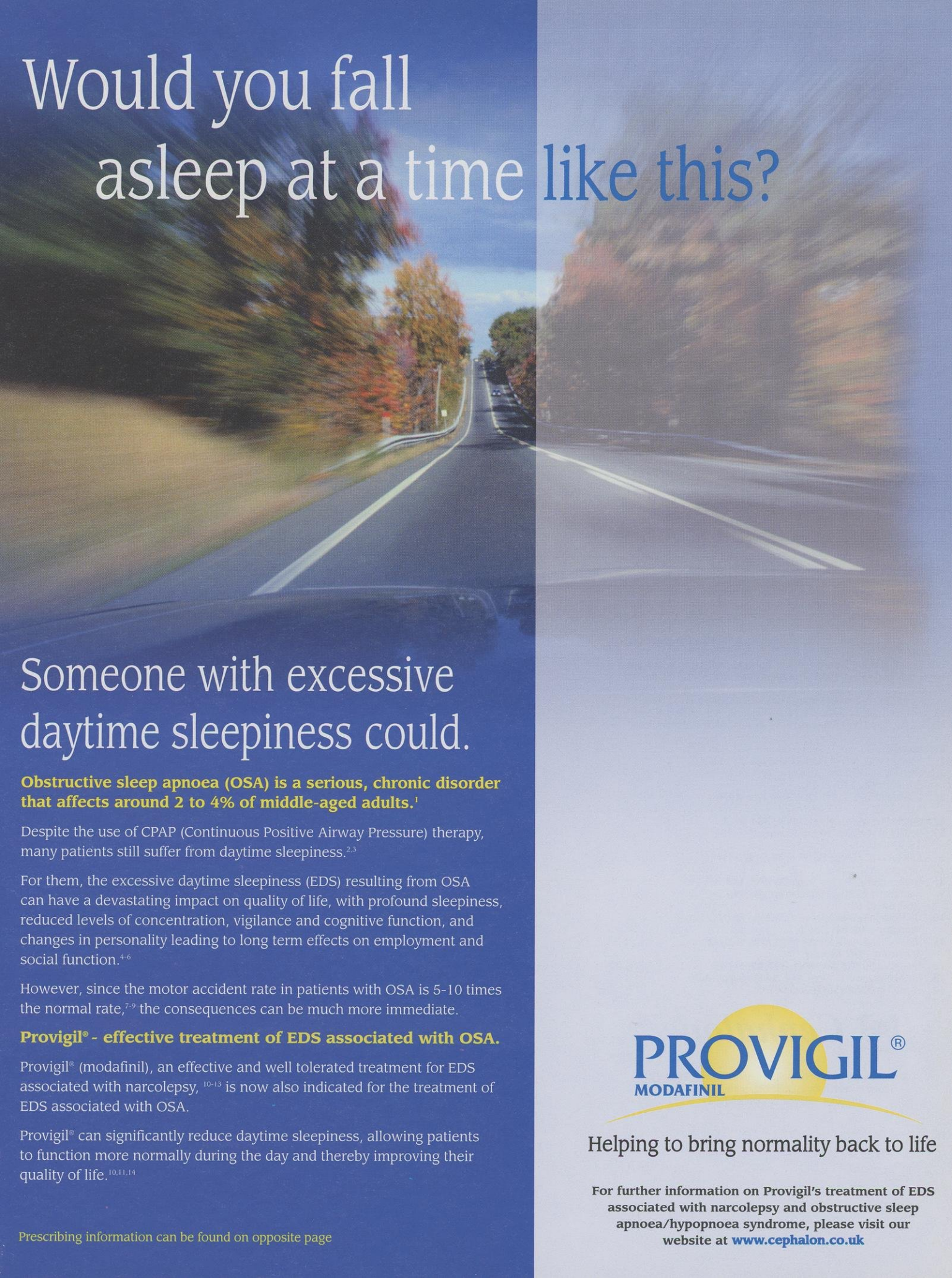
[s.l.]: [s.n.], 1997

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Would you fall asleep at a time like this?

Someone with excessive daytime sleepiness could.

Obstructive sleep apnoea (OSA) is a serious, chronic disorder that affects around 2 to 4% of middle-aged adults.¹

Despite the use of CPAP (Continuous Positive Airway Pressure) therapy, many patients still suffer from daytime sleepiness.^{2,3}

For them, the excessive daytime sleepiness (EDS) resulting from OSA can have a devastating impact on quality of life, with profound sleepiness, reduced levels of concentration, vigilance and cognitive function, and changes in personality leading to long term effects on employment and social function.⁴⁻⁶

However, since the motor accident rate in patients with OSA is 5-10 times the normal rate,⁷⁻⁹ the consequences can be much more immediate.

Provigil® - effective treatment of EDS associated with OSA.

Provigil® (modafinil), an effective and well tolerated treatment for EDS associated with narcolepsy,¹⁰⁻¹³ is now also indicated for the treatment of EDS associated with OSA.

Provigil® can significantly reduce daytime sleepiness, allowing patients to function more normally during the day and thereby improving their quality of life.^{10,11,14}

Prescribing information can be found on opposite page



PROVIGIL®
MODAFINIL

Helping to bring normality back to life

For further information on Provigil's treatment of EDS associated with narcolepsy and obstructive sleep apnoea/hypopnoea syndrome, please visit our website at www.cephalon.co.uk

UK ABBREVIATED PRESCRIBING INFORMATION:

PROVIGIL® 100 mg/200 mg Tablets

Please refer to UK Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** White to off-white tablets containing modafinil 100 mg or modafinil 200 mg (indicated by '100' or '200' debossed on one side). **Indication:** Excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnoea. **Dosage:** *Adults:* 200 - 400 mg daily either as two divided doses in the morning and at noon or as a single morning dose according to response. *Elderly:* Treatment should start at 100 mg daily, which may be increased subsequently to the maximum adult daily dose in the absence of renal or hepatic impairment. *Severe renal or hepatic impairment:* Reduce dose by half (100 - 200 mg daily). *Children:* See contra-indications. **Contra-indications:** Use in pregnancy and lactation, children, uncontrolled moderate to severe hypertension, arrhythmia, hypersensitivity to modafinil or any excipients used in Provigil. **Warnings and precautions:** Patients with major anxiety should only receive Provigil treatment in a specialist unit. Sexually active women of childbearing potential should be established on a contraceptive programme before taking Provigil. Blood pressure and heart rate should be monitored in hypertensive patients. In patients with obstructive sleep apnoea, the underlying condition (and any associated cardiovascular pathology) should be monitored. Provigil is not recommended in patients with a history of left ventricular hypertrophy nor in patients who have experienced mitral valve prolapse syndrome when previously receiving CNS stimulants. This syndrome may present with ischaemic ECG changes, chest pain or arrhythmia. Studies of modafinil have demonstrated a low potential for dependence, although the possibility of this occurring with long - term use cannot be entirely excluded. **Drug interactions:** Modafinil is known to induce CYP3A4/5 (and to a lesser extent, other) enzymes and so may cause clinically significant effects on other drugs metabolised via the same pathways. The effectiveness of oral contraceptives may be impaired through this mechanism. When these are used for contraception, a product containing at least 50 mcg ethinylloestradiol should be taken. Certain tricyclic antidepressants and selective serotonin reuptake inhibitors are largely metabolised by CYP2D6. In patients deficient in CYP2D6 (approximately 10% of the population) a normally ancillary metabolic pathway involving CYP2C19 becomes more important. As modafinil may inhibit CYP2C19 lower doses of antidepressants may be required in such patients. Care should also be observed with co-administration of other drugs with a narrow therapeutic window, such as anti-convulsant or anticoagulant drugs. **Side effects:** *Very common (>10%)* - headache, nervousness. *Common (>1%)* - insomnia, anxiety, dizziness, somnolence, depression, abnormal thinking, confusion, paraesthesia, hypertonia, nausea, dry mouth, diarrhoea, decreased appetite, dyspepsia, constipation, tachycardia, palpitation, vasodilatation, asthenia, chest pain, abdominal pain and blurred vision. Dose related increases in alkaline phosphatase and gamma glutamyl transferase have been observed. (See SmPC for uncommon side effects). **Basic NHS Cost:** Pack of 30 blister packed 100 mg tablets: £60.00. Pack of 30 blister packed 200 mg tablets: £120.00 **Marketing authorisation numbers:** PL 16260/0001 Provigil 100 mg Tablets; PL 16260/0002 Provigil 200 mg Tablets. **Marketing authorisation holder:** Cephalon UK Limited. **Legal category:** POM. **Date of preparation:** November 2002. Provigil and Cephalon are registered trademarks. Full prescribing information, including SmPC, is available from Cephalon UK Limited, 11/13 Frederick Sanger Road, Surrey Research Park, Guildford, Surrey UK GU2 7YD, Medical Information Freefone 0800 783 4869 (ukmedinfo@cephalon.com).

References:

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