

# Prescribing...

## Hot Topics

- ✚ The MHRA has highlighted important new information and strengthened warnings on valproate ▼ treatment.
- ✚ A new review has reported that stopping smoking was associated with improvements in mental health. The effect sizes seen were similar to those achieved using prescribed antidepressant treatment.

### 1. Warnings and advice on valproate ▼ treatment

The Medicines and Healthcare products Regulatory Agency (MHRA) has highlighted important new information and strengthened warnings associated with medicines related to valproate, valproic acid and valproate semisodium used during pregnancy.

This follows strengthened warnings from the European Medicines Agency (EMA) on the use of valproate medicines in women and girls. A recent review found developmental problems in up to 30-40% of preschool children exposed to valproate in utero, including delayed walking and talking, memory problems and lower intellectual ability. Exposure to valproate has also been linked with an increased risk of autistic spectrum disorder, childhood autism and attention deficit hyperactivity disorder. Additionally, about 11% of infants exposed to valproate in utero have malformations at birth, such as neural tube defects and cleft palates.

The MHRA has provided the following advice for healthcare professionals:

- Valproate should not be prescribed to female children and adolescents, women of childbearing potential or pregnant women unless other treatments are ineffective or not tolerated.
- Valproate treatment must be started and supervised by a doctor experienced in managing epilepsy or bipolar disorder.
- The benefits of valproate need to be carefully balanced against the risks when prescribing valproate for the first time, at routine treatment reviews, when a female child reaches puberty, and when a woman plans a pregnancy or becomes pregnant.
- All female patients should be informed of and understand the risks of valproate treatment during pregnancy. They should also be aware of the importance of using effective contraception, the need for regular reviews of treatment, and the need to rapidly consult a healthcare professional if they are planning a pregnancy or become pregnant.

Information booklets are also available for healthcare professionals and for patients from the

MHRA. In addition, valproate is now a black triangle medicine and being subject to additional monitoring, all suspected adverse reactions should be reported. Healthcare professionals should ensure that they are familiar with this advice.

## **2. Stopping smoking and mental health**

The physical health benefits associated with stopping smoking are well established. It is estimated that smokers lose more than 10 years of life, but that stopping smoking by 40 years old reduces that loss by approximately 90%. Even stopping by about 60 years old reduces that loss approximately 40%.

A systematic review has suggested that smoking cessation is associated with improvements in measures of mental health compared with continuing to smoke. The meta-analysis included 26 studies that assessed mental health with questionnaires, and the reviewers extracted data on change in mental health between baseline and follow-up. Follow-up mental health scores were measured between 7 weeks and 9 years after baseline. Compared with people who continued to smoke, those who stopped smoking had statistically significant decreases in anxiety (standardised mean difference [SMD] -0.37, 95% CI -0.70 to -0.03); depression (SMD -0.25, 95% CI -0.37 to -0.12); mixed anxiety and depression (SMD -0.31, 95% CI -0.47 to -0.14); and stress (SMD -0.27, 95% CI -0.40 to -0.13).

Psychological quality of life increased (SMD 0.22, 95% CI 0.09 to 0.36), as did positive affect (SMD 0.40, 95% CI 0.09 to 0.71), between baseline and follow-up in those who stopped smoking compared with those who continued to smoke.

About half the studies enrolled smokers from the general population, while others enrolled people with psychiatric disorders, people with chronic physical conditions, pregnant women and patients after surgery. There was no evidence that the effect sizes differed across the different populations.

The authors comment that the effect sizes seen were similar to those achieved using antidepressant treatment for mood and anxiety disorders.

The results of this review of observational data are encouraging and may provide extra motivation for islanders who smoke but wish to quit. However it is not possible to conclude that the changes were directly caused by stopping smoking. Some commentators have suggested that the results were less reliable in patients with mental health issues, while others questioned whether improved mood facilitated smoking cessation.

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**References : Drugs and Therapeutics Bulletin April 2015 Vol 3 Nr 4**