

Sleep disorder drug modafinil linked to increased risk of birth defects and also to reduced effectiveness of contraception

Press release

Women using modafinil are being warned of an increased risk of birth defects associated with modafinil use during pregnancy.



- Modafinil (Provigil) causes an approximate 15% likelihood of birth defects when taken during pregnancy; this compares with 3% in the general population
- Evidence that modafinil also reduces effectiveness of oral contraception
- Healthcare professionals treating narcolepsy with modafinil are also being reminded of the need to ensure patients are taking effective measures to prevent pregnancy

The warning comes from the Medicines and Healthcare products Regulatory Agency (MHRA) following careful [ongoing review of the risks](#). The drug may also reduce the effectiveness of oral contraception. Women taking modafinil should take effective measures to prevent pregnancy and discuss their contraception options with their healthcare professional.

This new advice is based on reports from a US study (of 61 babies exposed to modafinil in pregnancy) which showed that use of modafinil during pregnancy by women with narcolepsy possibly caused congenital malformations (including congenital heart defects, hypospadias, and orofacial clefts) in affected children.

Modafinil is a prescription-only medicine that is licensed only for the treatment of narcolepsy, a chronic disorder associated with sudden sleep that can cause serious disturbances to a patient's quality of life. As with any drug, there can be side effects associated with its use, including for modafinil psychiatric disorders (depression, suicidal behaviours, and

psychosis) serious skin reactions and cardiovascular disorders.

Dr Sarah Branch, director of MHRA's Vigilance and Risk Management of Medicines division said:

It is important that women are aware of the increased risk of congenital malformations associated with taking modafinil during pregnancy.

Modafinil can reduce the effectiveness of many hormonal contraceptives, including the pill. Women should discuss their options with their healthcare professional and continue to use their contraceptive for 2 months after stopping modafinil.

If you have any concerns, you should speak to your healthcare professional.

Patient safety is our highest priority. We strongly encourage anyone to report any side effects, from this or any medicine, to our [Yellow Card scheme](#).

Minister for Women's Health and Patient Safety Nadine Dorries said:

It is crucial that everybody is aware of the potential side effects of any medication they are taking.

Modafinil should only be taken when prescribed by a healthcare professional to treat narcolepsy and it is important all women taking it are aware of the potential risks including reducing the effectiveness of oral contraceptives and possible birth defects.

I urge all those taking modafinil to educate themselves on the side effects and potential risks, and to contact a healthcare professional if they are concerned.