

Modafinil in women of childbearing potential



Why have I been prescribed Modafinil?

Modafinil is taken by individuals who suffer from narcolepsy.

Narcolepsy is a long-term condition which causes excessive sleepiness during the day and may disrupt sleep at night. You can also have sleep attacks where you fall asleep at inappropriate times during the day without any warning.

Please also read the patient information leaflet on Modafinil available from the sleep centre and the pharmacy department.

What is Modafinil and what does it do?

Modafinil is a wake-promoting agent. It can be used to treat some of the symptoms of narcolepsy. Although there is no cure for narcolepsy, Modafinil can help to control your symptoms.

Modafinil promotes wakefulness by stimulating your brain to increase alertness and reduce excessive sleepiness during the day.

What is the problem with Modafinil and contraceptives?

Modafinil interacts with certain types of contraceptives to make them less effective which will increase your chances of getting pregnant.

Modafinil can also cause birth defects in an unborn child and must never be used if you are planning to become pregnant.

It is very important to make sure you are using the right contraceptive method when taking Modafinil. Please read the section "I am thinking of getting pregnant, what should I do?" below.

Modafinil is known as an 'enzyme-inducer' which means it increases the activity of enzymes found in your liver that are also used to break down your contraceptive. When the activity of these enzymes is increased, the contraceptive in your body is broken down more quickly giving it less time to work. There are no large-scale trials that have specifically tested Modafinil with the various contraceptives available. We do have trials that have investigated other medicines that are also 'enzyme-inducers' with contraceptives and we have the evidence to show contraceptives become less effective with these 'enzyme-inducers'.

The advice is based on what we predict will also happen with Modafinil and is supported by the Faculty of Sexual Health and Reproduction Medicine of The Royal College of Obstetrics and Gynaecology.

The table below indicates:

which contraceptives are **not** effective with Modafinil 🔀

and which ones **are** considered safe to continue using 📿

Types of contraceptive	Form of contraceptive	Examples	Safe to continue using?
Combined hormonal contraceptives	Combined oral contraceptives ('the pill')	Yasmin® Cilest® Mycrogynon® 30 ED Femodene® ED Logynon® Qlaira®	\otimes
	Transdermal Patch	Evra	\otimes
	Vaginal delivery system (the 'vaginal ring')	NuvaRing SyreniRing	\otimes

Progesterone- only hormone contraceptives	Progesterone-only oral contraceptives (the 'mini pill') including emergency contraception	Desogestrel Cerazete Zelleta Levonorgestrel 30 Lovonelle one step Ellaone	⊗
	Progesterone-only Intrauterine system (IUD) (the 'coil')	Mirena® Kyleena® Levosert® Jaydess®	\odot
	Subdermal Implant	Nexplanon®	⊗
	Depot Medroxyprogesterone acetate (DMPA)	Depot-Provera Sayana Press	\oslash
	Depot Norethisterone enantate	Noristerat [®]	\odot
Non-hormonal contraceptives	Intra-uterine contraceptive device- copper (IUD-Cu) (the 'coil') including as an emergency contraceptive	TT380° Slimline Multiload° UT380 standard° Flexi-T° 300 Neo-Safe° T380	${igodot}$

If you are prescribed Modafinil you must inform your consultant which contraceptive method you are using. Your consultant will advise you to speak to your GP if an alternative method is required while taking Modafinil. Modafinil will not be prescribed until an effective method of contraception is being used.

Can I use the barrier method when I am taking Modafinil?

The barrier method, which includes condoms, diaphragms, caps that can be used along-side a spermicide (e.g. Gygel), as well as the female condom Femidome[®], are considered less reliable forms of contraception. Although they do not interact with Modafinil, using them alone may not prevent you from getting pregnant. We advise you not to rely on these methods while taking Modafinil.

How long must I use contraception for when taking Modafinil?

You must continue using effective contraception as long as you are still taking Modafinil.

If you stop Modafinil for any reason, you must continue using effective contraception for 2 months after stopping. This is because your body needs time for the enzyme activity, which Modafinil interferes with, to return to normal.

I am thinking of becoming pregnant, what should I do?

Modafinil has been reported to cause congenital defects to an unborn child. These include heart defects, lip and cleft palate and other abnormalities affecting boys.

You must not take Modafinil if you are planning to become pregnant. Talk to your consultant about the potential alternatives to Modafinil.

If you are already taking Modafinil and plan to become pregnant, you must discuss this with your consultant as soon as possible. This is so

that a plan can be arranged on how you can safely stop Modafinil and manage your narcolepsy symptoms.

When stopping Modafinil you will still need to continue using effective contraception for 2 months after stopping to ensure Modafinil is completely washed out of your body and your liver enzyme levels return to normal, before attempting to become pregnant.

Can I take Modafinil when I am breastfeeding?

There are no studies available that examine the levels of Modafinil in human breastmilk but from animal studies, Modafinil is present in milk. Therefore **you should not breastfeed while taking Modafinil**.

Will Modafinil affect my fertility?

There are no clinical trials to investigate whether Modafinil can affect fertility in humans, but animal studies show that Modafinil does not lead to fertility problems.

If you are worried about anything raised in this leaflet speak to your consultant or pharmacist who can advise you further.

Useful sources of information

Contraception choices- <u>www.contraceptionchoices.org</u> is a website developed by healthcare professionals from the University College London that provides information on the different contraceptive options, designed to help women and couples decide which method of contraception might suit them best. Please note this website does not give advice on which contraception is suitable when taking Modafinil. You should continue to follow the advice in this leaflet and speak to your GP.

Contact us

If you have any questions about your sleep disorder please contact the sleep disorder centre,

telephone: 01342 305420

email tqv-tr.qvhsleepinformation@nhs.net

Monday to Friday, 8:30am to 5:00pm.

Pharmacy Medicines Helpline

If you have any questions or concerns about your medicines, please speak to the staff caring for you or call our medicines helpline.

telephone: 01342 041 04215

9:00am to 5.30pm, Monday to Friday

Please ask if you would like this leaflet in larger print or an alternative format.

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