

Modafinil linked to increased risk of birth defects and also to reduced effectiveness of contraception

Modafinil (Provigil) causes an approximate 15% likelihood of birth defects when taken during pregnancy; this compares with 3% in the general population.

The warning comes from the Medicines and Healthcare products Regulatory Agency (MHRA) following careful on-going review of the risks. Healthcare professionals are advised that:

- modafinil potentially increases the risk of congenital malformations (including congenital heart defects, hypospadias, and orofacial clefts); modafinil should not be used in pregnancy and alternative treatment options for narcolepsy should be considered
- women of childbearing potential must use effective contraception during treatment and for 2 months after stopping modafinil
- modafinil may reduce the effectiveness of steroidal contraceptives, including oral contraceptives, therefore alternative or concomitant methods of contraception are required

Further information can be found here: (<u>https://www.gov.uk/drug-safety-update/modafinil-provigil-increased-risk-of-congenital-malformations-if-used-during-pregnancy</u>)

Roflumilast (Daxas) classified as RED on the Rotherham CCG Traffic Light System

Roflumilast, is an add-on to bronchodilator therapy, recommended for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis. NICE recommends Roflumilast should be started by a specialist in respiratory medicine.

Due to the severity of the COPD symptoms at the time Roflumilast will be considered as a therapeutic option for patients, the use of Roflumilast has been classified as RED (all prescribing and monitoring to be undertaken in secondary care). The Rotherham CCG Traffic light document has been amended accordingly.

Docusate Capsules and Liquid Out of Stock

Docusate capsules and oral liquid are currently out of stock, with supplies likely to come back by mid to late December.

Advice to prescribers:

If the patient is on multiple agents, an option would be to slightly increase the dose of the other agents until patients manage to get a resupply of docusate. Although clinicians should be aware of the likelihood of increase in the side effects of those agents: bisacodyl/senna – stomach cramps, macrogol/lactulose – bloating & soft unformed stools.

For patients only on docusate, then look the cause – any slowing of peristalsis due to medication (e.g. opioids) or immobility then consider bisacodyl in the short term. If not then macrogol is an option. The CCG Laxative guidelines can help with specific indications: http://www.rotherhamccg.nhs.uk/Downloads/Top%20Tips%20and%20Therapeutic%20Guidelines/Therapeutic%20Guidelines/Laxative%20Guidelines%20update%20Nov%202015.pdf

Do not use lactulose (unless alcohol liver disease to prevent encephalitis) – it ferments in the gut and is unpleasant for a majority of patients – macrogol half can be used if only a small amount of softening is required.

Bupropion (Zyban): risk of serotonin syndrome with use with other serotonergic drugs

Cases of serotonin syndrome have been identified in associated with bupropion, especially in overdose or when bupropion is administered with other drugs with a serotonergic effect.

The MHRA has provided the following advice to healthcare professionals:

- cases of serotonin syndrome have been reported when bupropion is administered with other serotonergic drugs, for example
 - selective serotonin reuptake inhibitors (SSRIs)
 - serotonin norepinephrine re-uptake inhibitors (SNRI)
- if starting a serotonergic drug in patients taking bupropion, remind patients of the milder symptoms of serotonin syndrome at initiation of treatment and at any change of dose and the importance of seeking medical advice if they occur

Further information can be found here: <u>https://www.gov.uk/drug-safety-update/bupropion-zyban-risk-of-serotonin-syndrome-with-use-with-other-serotonergic-drugs</u>

Combined Oral Contraceptive Shortage and Alternates

Advice on alternatives to contraceptives that are currently in short supply

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PRODUCT	estrogen	progestogen	Expected	ALTERNATIVE
AFFECTED			resupply	
Ethinyloestradiol/norethisterone all COC including phasic COC are unavailable with no direct equivalent alternative				
BREVINOR Ethinylestradiol Norethisterone Consider COC containing				
BILLAINON	35mcg	500mcg		alternative progestogen i.e.
NORIMIN	Ethinylestradiol	Norethisterone	1	Cilique or Lizinna
	35mcg	1000mcg		(ethinylestradiol 35 mcg/
	Joineg	looning		norgestimate 250 mcg).
SYNPHASE (phasic)	Ethinylestradiol 35mcg	Norethisterone 500mcg/1000mcg	Mid- January 2021	Consider COC containing alternative progestogen -
				levonorgestrel i.e. Logynon or TriRegol (ethinylestradiol 30mcg/40mcg/30mcg and levonorgestrel 50mcg/57mcg/125mcg).
FEMODETTE	Ethinylestradiol 20mcg	Gestodene 75mcg	Mid- January 2021	Consider alternative brand containing same active ingredients in the same dose e.g. Millinette, Sunya, Akizza – please check with local pharmacy which brand currently obtainable before issuing Rx.
NORINYL-1	Mestranol 50mcg	Norethisterone 1000mcg	End of February 2021	No direct equivalent available. Consider switch to ethinylestradiol based COC if appropriate or alternative form of contraception i.e copper IUD or POP
YIZNELL	Ethinylestradiol 30mcg	Drospirenone 3000mcg	Mid- January 2021	Consider alternative brand containing same active ingredients in the same dose i.e. Yacella, Lucette, Yasmin, Dretine – please check with local pharmacy which brand currently obtainable before issuing Rx.