

Drug Safety Supplement

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Drug treatment requiring effective contraception

Advice for all healthcare professionals

- No drug is without risk in early pregnancy [1].
- The likelihood of pregnancy is not constant and can vary with changes in a girl's or woman's circumstances during treatment [2].
- For girls and women who are pregnant or planning a pregnancy, and men trying to father a child:
 - Encourage them to talk to a healthcare professional about prescribed medicines that they or their partner are taking. This includes any over the counter or herbal or complementary medicines, and recreational drugs.
 - Advise them to talk to their doctor before stopping a prescribed medicine.

Advice for prescribers

- The harmful effects from exposure to drugs in pregnancy might be considered significant by girls and women of child-bearing potential, and by men who are trying to father a child.
- The likelihood of pregnancy should be assessed before each prescription of a medicine with known teratogenic potential [2].
- The outcomes of a decision taken with the patient, their carer, or both to address the risks, benefits, and measures taken to minimise harmful exposure should be clearly documented and shared as appropriate.
- Whenever reasonably practicable, treatment with a medicine with teratogenic potential should be delayed until pregnancy has been excluded [2].

Highly effective contraception [3]

- Girls and women of reproductive age taking a potentially teratogenic drug should be advised to use highly effective contraception during treatment and after treatment until the risk of harmful exposure has passed. Refer to the [BNF](#) and [electronic Medicines Compendium](#) for up to date information of the risk with specific drugs.
- **No method of contraception can be considered to be 100% effective.** Highly effective contraception has a typical-use failure rate of less than 1%. Copper intrauterine devices, levonorgestrel intrauterine systems, progestogen-only implants (with no interacting drugs that reduce effectiveness), and male or female sterilisation are considered to be highly effective. Additional contraceptive precautions are not required but condoms will further reduce the risk of pregnancy and protect against sexually transmitted infections.
- If a girl's or woman's preferred choice is combined hormonal contraception, the progestogen-only pill, or depot medroxyprogesterone acetate then she must use additional contraceptive precautions and not take any interacting drugs that reduce effectiveness.
- Barrier methods, withdrawal, and fertility awareness alone are not recommended.

Medicines information

Risk assessment in routine clinical review is based on the following considerations:

- Resources providing information on the harmful effects of drugs in pregnancy may help inform a clinical decision to prescribe but should not replace clinical judgement.
- Absence of information does not imply safety [1].

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Resources

[BNF](#) and [BNF for Children](#)

Identify drugs which may have harmful effects in pregnancy and the trimester of risk or are not known to be harmful [4].

[electronic Medicines Compendium](#)

Information about medicines licensed in the UK.

[Medicines and Healthcare products Regulatory Agency](#)

Vigilance, alerts and guidance on drug safety. Report any suspected adverse reactions to medicines.

- [Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed?](#)
- [Drug Safety Update](#)
- [Yellow Card](#)

[UK teratology information service](#)

Evidence based information on foetal risk following exposures.

[Faculty of Sexual and Reproductive Healthcare](#)

Standards and guidance for sexual and reproductive health.

- [Contraception for women using known teratogenic drugs or drugs with potential teratogenic effects](#)

[Specialist Pharmacy Services](#)

Expert advice to improve the use of medicines.

- [What is a suitable combined oral contraceptive pill in a patient who is taking hepatic enzyme-inducing drugs, such as carbamazepine, phenytoin, rifampicin or rifabutin?](#)

[UK Medicines Information directory](#)

Contact information for people related to Medicines Information.

- [UKMi Specialist Centres for Drugs in Pregnancy](#)
- [North West Region](#)

References

1. BNF (2019). [Prescribing in pregnancy](#). [Accessed 25 Mar 2019]
2. MHRA (2019). [Medicines with teratogenic potential: what is effective contraception and how often is pregnancy testing needed?](#) [Accessed 09 Apr 2019]
3. FSRH (2018). [Contraception for women using known teratogenic drugs or drugs with potential teratogenic effects](#). [Accessed May 2019]