

Prescribing tip for information

**Medicines with teratogenic potential:  
what is effective contraception and how often is pregnancy testing needed?**

Some medicines have the potential to increase the risk of birth defects and development disorders (teratogenic potential) when taken during pregnancy. The risk is especially high during the first trimester when a woman may not know she is pregnant. The Medicines and Healthcare products Regulatory Agency (MHRA) has [issued guidance](#) about the need for effective contraception when these medicines are prescribed and the frequency with which pregnancy testing should be undertaken. Examples of medications with teratogenic potential include antiepileptics, statins, lithium, antivirals for HIV treatment, oral Retinoids, Thalidomide and some antifungals. Refer to the [BNF](#) or the [product SPC's](#) for more specific drug information.

**NB. Sodium Valproate, Oral Retinoids and Thalidomide** have the **additional requirement** of women needing to be part of a [Pregnancy Prevention Programme](#). Refer to the [product SPC's](#) for more specific drug information.

Women prescribed a medicine with teratogenic potential should **be advised of the risks and encouraged to use the most effective contraception method considering her personal circumstances.**

**Highly effective methods, (typical user failure rate in first year of 1%)**

- Male or female sterilisation
- Long-acting reversible contraceptive (LARC) methods (intrauterine devices and implants)
- Progestogen-only injections **(only if repeat prescriptions are documented as having been administered on schedule by a healthcare professional. If injections are administered late typical user failure rate rises to 6%)**

**Effective methods, (typical user failure rate in first year of 9%)**

- Combined hormonal contraceptive (pills, patches, or vaginal rings)
- Progestogen-only pills.
- **An additional barrier method is advised with an effective contraceptive method.**

**NB. Methods used at the time of sexual intercourse or based on fertility awareness have higher typical-user failure rates, are not classed as 'effective' for use with medicines with teratogenic potential and should not be relied upon alone.**

Despite this advice the MHRA continues to receive reports of inadvertent exposure to such medicines during early pregnancy. Possible reasons could be that a woman is unaware she is pregnant at the start of treatment or be in the early stages of pregnancy at the time of repeat prescribing due to contraceptive failure. To avoid inadvertent exposures the MHRA advises

- Assess the risk of pregnancy prior to each teratogen prescription
- Perform a pregnancy test in line with guidance.

The Medicines for Women's Health Expert Advisory Group of the Commission on Human Medicines has developed [an aide-memoire table](#). The table provides prescribers with a summary of the pregnancy testing advice for the most common contraceptive methods and is colour-coded according to the most reliable methods.

The Best Use of Medicines in Pregnancy 'Bumps' website <https://www.medicinesinpregnancy.org/> provides reliable, evidence-based, and accurate information about use of medicines in pregnancy and has freely available patient information leaflets.

**To contact the Medicines Optimisation Team please phone 01772 214302**