

MHRA requires enrolment in a pregnancy prevention programme during use of sodium valproate

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As of today, the [Medicines and Healthcare Products Regulatory Agency \(MHRA\) has changed its regulatory position on medicines containing sodium valproate](#), usually prescribed for treating epilepsy and bipolar disorder. MHRA advises that if a woman of childbearing age is to be prescribed sodium valproate, she must be enrolled in a pregnancy prevention programme (PPP).

Valproate medicines do not interfere with or reduce the efficacy of any contraceptive method, and contraception does not alter valproate function. However, valproate's teratogenic effects cause significant risk of birth defects and persistent developmental disorders. Therefore, it is extremely important to reduce the number of planned and unplanned pregnancies exposed to valproate.

The [2017 FSRH Guidance on Drug Interactions with Hormonal Contraception](#) advises that women of reproductive age who are taking known teratogenic drugs or drugs with potential teratogenic effects should always be advised to use highly effective contraception both during treatment and for the recommended timeframe after discontinuation to avoid unplanned pregnancies.

Methods of contraception which are considered 'highly effective' in this context include the long-acting reversible contraceptives (LARCs) copper intrauterine device, levonorgestrel intrauterine system and progestogen-only implant as well as male and female sterilisation, all of which have a failure rate of less than 1% with typical use. Women using implants must not take any interacting drugs that could reduce contraceptive effectiveness. If pills, patches, vaginal rings or injectables are used then an additional barrier contraception, such as condoms, are advised and regular pregnancy testing, considered. Women should also seek advice from a specialist, who will carry out a pregnancy risk assessment and provide evidence-based advice on the most suitable method for them.

What are the implications for daily practice?

MHRA states that all women and girls who are prescribed valproate should contact their GP and arrange to have their treatment reviewed. No woman or girl should stop taking valproate without medical advice.

The agency advises that healthcare professionals who seek to prescribe valproate to their female patients must make sure women are enrolled in the PPP. This includes the completion of a signed risk acknowledgement form when their treatment is reviewed by a specialist annually. Prescribers will be expected to do the following:

- Discuss known risks with all female patients
- Ensure they and the patient have signed the risk acknowledgement form
- Exclude pregnancy before initiation
- Arrange for highly effective contraception if necessary
- Ensure she sees a specialist at least once a year

The Chief Medical Officer, Dame Sally Davies, has written today to all healthcare professionals in England via an alert issued through the Central Alerting System to advise them of the changes and her expectation of the actions they are required to take. A pdf copy of the CMO's letter to healthcare professionals in England can be accessed directly [here](#). The Chief Medical Officers of Scotland, Wales, and Northern Ireland will each be issuing their own versions of this letter.

MHRA has also included details in the Drug Safety Update published today, which you can read [here](#).