



## Advice for male patients on valproate to use contraception

This is for healthcare professionals to provide to male patients taking valproate as well as their families and caregivers.

Always read the information that comes with your medicine and talk to a doctor, nurse, or pharmacist if you have any concerns.

### Quick advice

- Do not stop taking valproate unless your specialist advises you to because of the need to keep your condition under control.
- Use condoms while on valproate and for 3 months after stopping – ask your female sexual partner to also use birth control to prevent them from becoming pregnant
- Attend your next appointment, when invited to do so, to discuss the risks and your options
- Let your doctor know if you are planning to father a child and are on valproate.
- Do not donate sperm while on valproate or for 3 months after stopping valproate

### Valproate medicines

Sodium valproate, valproic acid or valproate semisodium are valproate medicines. Valproate medicines are used in treatment of epilepsy and bipolar disorder. Brands of valproate medicines are Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell.

### New information about fathering children on valproate

If you father a child while you are taking valproate, there is a potential small increased risk of the child being diagnosed with problems with their mental or movement development (neurodevelopmental disorders).

A study of health records reported that around 5 in 100 children whose fathers were taking valproate at conception had a developmental disorder. This was compared to around 3 in 100 children whose fathers were taking lamotrigine or levetiracetam: two other anti-seizure epilepsy medicines. The study did not look at risks for children whose fathers did not take any medication.

Whilst this study doesn't prove that valproate use in men increased the risk of problems in children, it is an important safety concern that warrants action on a precautionary basis.



## Medicines & Healthcare products Regulatory Agency

### **What to do if you are taking valproate**

It is recommended that you and your female sexual partner should both use effective birth control (condoms and another form of female contraception). The reason you should use two forms of birth control is because condoms are not always effective at preventing unplanned pregnancy.

You should use birth control while you are taking valproate and for at least 3 months after stopping valproate. Allowing 3 months to pass after stopping valproate allows new sperm cells to be formed which have not been exposed to valproate. It is important to note that there are no data on risk after stopping valproate treatment and this needs further investigation.

At your next appointment have a discussion with your healthcare professional on the increased risks (which also include the potential for impaired fertility) and the treatments available at your regular appointment. If you are planning a child in the next year, your GP can refer you to a specialist for advice on other treatment options.

You should not donate sperm whilst taking valproate and for 3 months after stopping.

If your partner is pregnant or undergoing assisted conception, talk to a healthcare professional who can support your decisions regarding your treatment. If you have any concerns, please speak to a healthcare professional.

### **Fertility**

Valproate can affect fertility in male patients. This can make it more difficult to father a child. Changes to male fertility are usually reversible after valproate is stopped and may be reversible after reducing the valproate dose. However, we do not know if this is true for all patients. [More information is available in the valproate patient guide](#), which will be updated with advice about the information about fathering children on valproate in the coming months.

### **Valproate in female patients**

Valproate is known to be associated with a high risk of both birth defects and neurodevelopmental disorders in children if taken by a woman during pregnancy. In women who take valproate while pregnant, around 1 in 9 babies will have a birth defect and about 3 to 4 children in every 10 may have developmental problems.

Valproate must not be used in any woman or girl able to have children unless there is a Pregnancy Prevention Programme in place. Women on valproate should have an annual review of their treatment plan during which they should have a discussion with their specialist on the risks of taking valproate while pregnant. More advice is included in the [valproate patient guide](#).

### **Do not stop valproate or change your dose unless told to do so by a specialist.**

You can report any suspected adverse drug reactions associated with valproate to the MHRA through our [Yellow Card scheme](#).

Next review date: February 2025