

WHAT YOU SHOULD KNOW

This guide contains key information about the potential risk when fathering a child if you are treated with valproate.

Ask your doctor or pharmacist if you have any questions.

KEEP THIS GUIDE. YOU MAY NEED TO READ IT AGAIN.





What are the risks of taking valproate* when fathering a child

A study suggests that if you take valproate in the 3 months prior to conception, your child may have a higher risk of impaired mental and/ or motor development compared to children born to fathers who used lamotrigine or levetiracetam, other medicines that can be used to treat your disease.

In this study, around 5 children in 100 had such disorders when born from fathers treated with valproate, and around 3 children in 100 when born from fathers treated with the other medicines.

There are no data on this potential risk to children fathered more than 3 months after stopping valproate treatment (the time needed for new sperm to be formed).

What does this mean for you?

Your doctor will discuss with you (and/or your parent/caregiver) the potential risk when fathering a child if you are treated with valproate and the precautions associated with valproate use:

- The need to use **effective contraception** (birth control) for you and your female partner during the treatment and for 3 months after stopping valproate
- The need to consult your doctor to discuss alternative treatment options, as soon as you are planning to father a child and before discontinuing contraception (birth control)
- To not donate sperm during treatment and for 3 months after stopping treatment.

If your **female partner becomes pregnant** while you used valproate in the 3 months prior to conception, both of you should **contact the doctor** for counselling.

Do not stop your treatment without talking to your doctor. If you stop your treatment, your symptoms may become worse.

At treatment initiation and during an annual visit, your doctor will discuss these risks with you to ensure you know and understand the risks related to the use of valproate when fathering a child.

*This includes brands such as Epilim, Sodium Valproate Sandoz, Valpro EC and Valproate Winthrop.

PLEASE REFER TO THE CONSUMER MEDICINES INFORMATION (CMI)
LEAFLET FOR MORE DETAILED INFORMATION

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