

VALPROATE GUIDE FOR MALE PATIENTS

Read this guide along with the patient information leaflet which is included in each box of your medicine

This medicine will be referred to as valproate throughout this guide and covers the brands Epilim, Depakote, Alprolep, Belvo, Convulex, Dyzantil, Episenta, Epival, Syonell & Sodium Valproate (Crescent, Desitin, Strandhaven/Somex, Wockhardt).

WHAT YOU SHOULD KNOW

This guide contains key information about the risks of valproate.
Ask your doctor, nurse or pharmacist if you have any questions.

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

Information about the use of valproate in male patients can also be found online at www.medicines.org.uk by entering "valproate" in the search box and then clicking on "Risk Materials" next to any of the medicines listed. You can also search online for "MHRA valproate".

Risk minimisation material fulfils the conditions of the marketing authorisation and has been approved by MHRA.

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Medicines & Healthcare products Regulatory Agency

Do not stop taking valproate unless your specialist tells you to - this is because your condition may become worse, including an increased risk of seizure in those being treated for epilepsy and increased risk of relapse in those treated for bipolar disorder.

What are the risks to male patients of taking valproate?

Valproate is used to treat epilepsy and bipolar disorder.

Valproate can potentially cause:

- Male infertility (may be reversible after treatment is stopped or the dose is reduced for some patients).
- Toxic effects on the testes (testicles) of animals, such as reduction in testes weight - it is unclear what this means for humans.

What are the risks of taking valproate when conceiving a child?

A study suggests a possible risk of neurodevelopmental conditions (problems with early childhood development) in children born to fathers treated with valproate in the 3 months before conception.

In this study, around 5 children in every 100 had such disorders when born to fathers treated with valproate, as compared to around 3 children in every 100 when born to fathers treated with lamotrigine or levetiracetam (other medicines that can be used to treat your condition).

The study was not large enough to show which particular type of disorder children may be at risk of developing.

Other studies did not suggest an increased risk of mental developmental disorders (problems with early childhood development) in children born to fathers treated with valproate in the 3-4 months before conception. In these studies the risk was similar compared to children of fathers treated with lamotrigine or levetiracetam before conception.

Differences in how these studies were designed may explain the different results. Overall, it is not known whether any possible risk of childhood developmental disorders is caused by valproate itself or by other factors, such as the father's underlying medical condition.

What does this mean for me?

Your specialist will discuss the benefits and risks of valproate with you:

If you are aged under 55 years, you should only be started on valproate if your specialist has discussed with you and another specialist and agreed that your condition does not respond to other treatments or that the risks outlined above do not apply to you. This applies to those aged under 55 years because this is the age group most likely to be affected by the known risk of infertility.

If you are a patient, parent or a caregiver of a male child treated with valproate, a specialist will explain to you that there are studies showing toxic effects of valproate on the testes of animals receiving the medicine, it is unclear what this means for humans.

At the initial visit with your/your child's specialist, you will discuss and complete a Risk Acknowledgement Form to make sure you know and acknowledge the risk of male infertility or toxic effects of valproate on the testes of animals. As a precautionary measure, your /your child's GP or specialist will discuss with you the potential risk in children born to fathers treated with valproate in the 3 months before conception.

You should have regular appointments with your GP. During this visit your GP will discuss with you the precautions associated with valproate use. Depending on your individual situation, they may refer you to a specialist to discuss the possibility of other treatments that can be used to treat your condition. These switching discussions will only be completed by a specialist.

As a precaution and when applicable, your GP and specialist will also discuss with you:

- The need to consider a **barrier method** (condoms) for you **and** an **effective contraception** (birth control) for your female partner during valproate use and for 3 months after stopping valproate (the time needed for new sperm to be formed).
- The need to consult your doctor when you **are planning to conceive a child** and before stopping contraception (birth control).
- The possibility of other treatment options that can be used to treat your condition, depending on your individual situation.

Do not donate sperm when taking valproate or for 3 months after stopping valproate treatment.

Talk to your GP or specialist if you are thinking about having a baby.

If your **female partner becomes pregnant** while you used valproate in the 3 months period before conception and you have questions, **contact your** GP or specialist.

TO BE READ ALONGSIDE THE PIL IN THE BOX OF YOUR MEDICINE.

Other sources of information

You may find the following organisations helpful if you are looking for information about epilepsy or bipolar disorder and how to effectively manage your condition:

Epilepsy Action
www.epilepsy.org.uk
0808 800 5050

Epilepsy Society
www.epilepsysociety.org.uk
0300 102 0024

Young Epilepsy
www.youngepilepsy.org.uk

Abstract of Post-Authorisation Safety Study - Paternal exposure (VALNAC09345)
https://catalogues.ema.europa.eu/system/files/2024-02/Valproate_PASS_Abstract_V2.0_0.pdf

Bipolar UK
www.bipolaruk.org

Mind
www.mind.org.uk
0300 123 3393

SUDEP Action
www.sudep.org
01235 772 852

Keep this guide safe. You may need to read it again.

For further copies of this guide, please contact Sanofi Medical Information department on:

0800 035 2525 or email **UK-Medicalinformation@sanofi.com**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. You can talk to your doctor, pharmacist or nurse or you can also report side effects directly via the Yellow Card Scheme at **www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store.