



VALPROATE▼(EPILIM) GUIDE FOR MALE PATIENTS

*Read this guide
along with the leaflet
inside the medicine box*

VALPROATE▼(EPILIM)

WHAT YOU SHOULD KNOW

This guide contains key information about the potential risk of valproate▼(Epilim) when used by male patients in the 3 months before conception of a child.

Ask your doctor, nurse or pharmacist if you have any questions.

Electronic versions of this guide can also be found online at <https://medicinesauthority.gov.mt/>.

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

▼ This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. This will allow for quick identification of new safety information. . If you get any side effects, talk to your doctor. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Report any side effects to postlicensing.medicinesauthority@gov.mt or at www.medicinesauthority.gov.mt/adrportal or to PharmacovigilanceMalta@sanofi.com

**THIS GUIDE HAS BEEN APPROVED BY THE HEALTH PRODUCTS REGULATORY AUTHORITY
Malta Medicine Authority on 16 Jul 2024**

What are the risks of taking valproate▼(Epilim) when conceiving a child

A study¹ suggests a possible risk of movement and mental developmental (neurodevelopmental) disorders in children born to fathers treated with valproate (Epilim) in the 3 months before conception.

Movement and mental developmental disorders are problems with development that begin in early childhood such as being late to walk and talk, lower intelligence than other children of the same age, poor speech and language skills, autism or autistic spectrum problems, attention deficit and/or hyperactivity disorder.

In this study, around **5 children in every 100** had such disorders when born to fathers treated with valproate (Epilim), 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 (epilepsy/bipolar)).

Study Limitations

However, the study has limitations and therefore it is not entirely clear if the increased risk for movement and mental developmental disorders suggested by this study is caused by valproate (Epilim).

In addition the study was not large enough to identify a particular type of disorder children may be at increased risk of developing.

The risk for children born to fathers who stopped valproate (Epilim) treatment 3 months (the time needed to form new sperm) or longer before conception is not known.

1. Further information on this study is available through:
[www.hpra.ie/homepage/medicines/special-topics/valproate-\(epilim\)](http://www.hpra.ie/homepage/medicines/special-topics/valproate-(epilim))

What does this mean for me?

As a precautionary measure, your doctor will discuss with you the potential risk in children born to fathers treated with valproate (Epilim) in the 3 months before conception.

Your doctor will also discuss with you:

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

Do not stop taking your treatment without talking to your doctor, as your condition (epilepsy or bipolar disorder) could become worse. Sudden discontinuation of any treatment for epilepsy should be avoided as this may lead to seizures.

Do not donate sperm when taking valproate (Epilim) and for at least 3 months after stopping valproate (Epilim) treatment.

Talk to your doctor if you are thinking about having a baby.


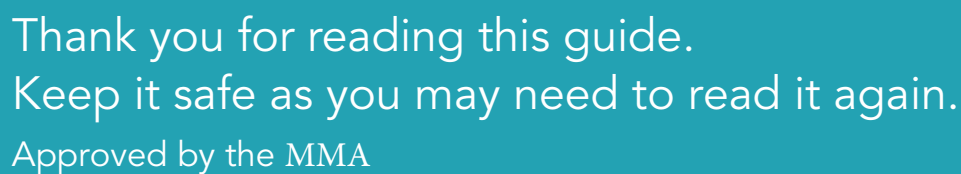

If your **female partner becomes pregnant** while you used valproate (Epilim) in the 3 months before conception and you have questions, **contact your doctor**.

You should **get regular appointments** with your doctor. During these appointments your doctor will discuss with you the precautions associated with valproate (Epilim) use and the possibility of other treatments that can be used to treat your condition, depending on your individual situation.

Your pharmacist will provide you with a **patient card** when your medicine is being dispensed to you.

It contains important information for both male and female patients who have been prescribed valproate (Epilim).

You should keep it safe so that you always know what to do.



Thank you for reading this guide.
Keep it safe as you may need to read it again.
Approved by the MMA

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