



HSE NATIONAL PROGRAMME

Specialist Perinatal

MENTAL HEALTH SERVICES

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MENTAL HEALTH SERVICES



Valproate in
women and girls
who could get
pregnant

IN CONJUNCTION WITH



Clinical Design
& Innovation
Person-centred, co-ordinated care



RC
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Valproate in women and girls who could get pregnant

About this leaflet:

Disclaimer: This leaflet provides information, not advice. You should read our full disclaimer on the back page before using this leaflet.

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This leaflet is for any girl or woman of child-bearing age who:

- has been offered a medication containing Valproate
- is currently taking a medication containing Valproate
- is currently taking a medication containing Valproate and who is pregnant and their partner, families and friends.

This leaflet will cover:

- why Valproate should not be used in anyone who could become pregnant
- what to do if you are taking Valproate and want to get pregnant
- what to do if you are pregnant and taking Valproate.

What is Valproate?

Sodium valproate is a medication developed in the 1970s for the treatment of epilepsy. Since the 1990s it has also been used to treat bipolar disorder.

What medicines contain Valproate?

Forms of Valproate, also called Sodium Valproate, are Valproic Acid (Semisodium Valproate) are found in the medicine called Epilim.

Valproate, pregnancy and Bipolar Disorder

Valproate is an effective medicine for the treatment of Bipolar Disorder.

However, if it is taken during pregnancy it can harm an unborn baby.

Valproate is much more likely to harm a baby than other medicines used for Bipolar Disorder ⁽¹⁾.

The higher the dose of Valproate, the higher the risk of harm ⁽²⁾.

Pregnancy does not protect you from becoming unwell with Bipolar Disorder. The risk of a relapse is high during pregnancy - and very high in the first few weeks after having a baby. The risk is particularly high if you aren't taking medication ⁽³⁾.

If you have a diagnosis of Bipolar Disorder, you are also more likely to have a Postpartum Psychosis ⁽³⁾.

This is a severe mental illness which usually starts in the first few weeks after birth, ***see our leaflet about: Postpartum Psychosis for more information.***

If you have Bipolar Disorder and want to plan a pregnancy, or are already pregnant, do see a psychiatrist - ideally a specialist Perinatal Psychiatrist, for specialist advice, care and treatment. This will help you to stay well during pregnancy, and after the birth.

Does Valproate affect fertility?

In women prescribed Valproate for epilepsy, Valproate has been shown to increase the rate of polycystic ovarian syndrome ⁽⁴⁾. This can make it more difficult to become pregnant. Also, this effect can persist after stopping Valproate.

What harm can Valproate cause to babies?

Valproate can harm babies in the womb. It can then cause problems with development and learning throughout a child's life.

- In women with no illness and taking no medication, around 2-3 babies in every 100 will have a birth defect.
- In women who take Valproate whilst they are pregnant, around 10 babies in every hundred (10%) will have a birth defect ^(5,6). These birth defects include:
 - spina bifida (where the bones of the spine do not join up properly).
 - cleft lip and cleft palate (where the upper lip or bones in the face are split).
 - abnormalities of the limbs, heart, kidney, urinary tract and sexual organs.
- In women who have taken Valproate whilst they were pregnant, 30-40 children in every hundred (30-40%) are likely to have developmental difficulties. This can include delay in learning to walk and talk, lower intelligence, poor speech and language skills and memory problems ^(7,8).
- Children whose mothers were taking Valproate when they were in the womb are more likely to have Autism and Autistic Spectrum Disorders (8,9). They may also be more likely to have Attention Deficit Hyperactivity Disorder (ADHD) ⁽¹⁰⁾.

What about taking folic acid?

Folic acid is recommended for all women planning pregnancy to help protect against Spina Bifida. However, even in high doses, it does not prevent any of the increased risk of birth defects ⁽¹¹⁾. High dose folic acid can also interfere with Valproate's effectiveness in Bipolar Disorder ⁽¹²⁾.

What is the guidance about taking Valproate for Bipolar Disorder?

There are other medicines that can be used to treat Bipolar Disorder that are much less likely to harm the baby. These should be prescribed for any woman who has the potential to get pregnant, even if she is not planning a pregnancy. The National Institute for Health and Care Excellence (NICE) ⁽¹³⁾ the Scottish Intercollegiate Guidelines Network (SIGN) ⁽¹⁴⁾, and the British Association of Psychopharmacology ⁽¹⁾ say that Valproate should not be prescribed to treat Bipolar Disorder in girls or women who are able to become pregnant.

Should a woman ever take Valproate to treat Bipolar Disorder?

The European Medicines Agency⁽¹⁵⁾ and the Health Products Regulatory Authority (HPRA)⁽¹⁶⁾ has recommended that, if you are able to have children, Valproate must not be used unless:

- You have had a conversation with the specialist who is going to prescribe the Valproate about your chances of becoming pregnant and the need for effective contraception throughout treatment
- You should have a pregnancy test before starting treatment with Valproate
- You must have a review of the Valproate treatment at least once a year by a specialist
- At each yearly review, you and the specialist will discuss the risks to an unborn baby
- At the start of treatment - and at each yearly review – you and the specialist must sign a risk acknowledgment form. This shows that everyone understands the risks of becoming pregnant whilst taking Valproate.

In rare cases, you might decide that, even with all the problems, the best plan for you is to continue taking Valproate. This could be because:

- You have no plans to become pregnant
- Other treatments have not been helpful
- You are extremely unlikely to get pregnant – e.g. because you have had a sterilisation.

If you, your family and your doctor, considering the guidance and the risk to babies, decide that Valproate is the best option to treat your Bipolar illness, then:

- You and your doctor need to be clear about the serious risks to the baby if you were to become pregnant
- You must have written information about these risks

- You must be sure that there is no chance of an unplanned pregnancy. If this involves using contraception, then it should be one of the more reliable forms of contraception such as an implant, coil or sterilisation.

Should I stop Valproate now?

If you could become pregnant, and you are taking Valproate to treat Bipolar Disorder, it is important that you do not stop the medication suddenly. This will increase your risk of becoming unwell. Make an appointment with the doctor who prescribes your Valproate. Together you can think about what medicine might be safer for you to take to treat your Bipolar illness.

What if I'm taking Valproate and I'm already pregnant?

If you are taking Valproate for Bipolar Disorder and you think you might be pregnant, don't stop your medication suddenly. Ask your psychiatrist or GP to refer you to a Perinatal Psychiatrist if there is one in your area. If not, you should see your psychiatrist, who can link with their perinatal psychiatrist or ask your GP to refer you to one. Together you can decide what medication would be safest for you to take for the rest of your pregnancy, and after you have your baby.

Further information/ online resources



Further information:

Withdrawal of, and alternatives to, valproate-containing medicines in girls and women of childbearing potential who have a psychiatric illness. RCPsych Position Statement PS04/18. December 2018. https://www.rcpsych.ac.uk/docs/default-source/improving-care/better-mh-policy/position-statements/ps04_18.pdf?sfvrsn=799e58b4_2.

Health Products Regulatory Authority (HPRA) 2018 Guidance Valproate use by women and girls – a toolkit including information for professionals, a patient booklet and patient card. [http://www.hpra.ie/homepage/medicines/special-topics/valproate-\(epilim\)](http://www.hpra.ie/homepage/medicines/special-topics/valproate-(epilim))

Health Service Executive (HSE) Clinical Design and Innovation – Valproate Information <https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/patient-information/valproate/>

Health Service Executive (HSE) Patient Guide on Valproate: <http://www.hpra.ie/docs/default-source/Valproate/patient-guide.pdf?sfvrsn=0>

National Centre for Mental Health, Bipolar UK & Action on Postpartum Psychosis: Bipolar disorder, pregnancy and childbirth Information for women, partners and families <https://www.app-network.org/>

HSE's Your Mental Health (<https://www2.hse.ie/mental-health/>). Find advice, information and support services for mental health and well-being.

Citizen's Information: <https://www.citizensinformation.ie/en/search/?q=pregnancy>
Your rights and entitlements from the citizen's information board.

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16. Health Products Regulatory Authority (HPRA) 2018

17. Royal College of Psychiatrists - RCPsych response to review into the use of sodium valproate for pregnant women - <https://www.rcpsych.ac.uk/news-and-features/latest-news/detail/2017/10/04/rcpsych-response-to-review-into-the-use-of-sodium-valporate-for-pregnant-women?searchTerms=Valporate>

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If you have questions about any medical matter, you should consult your doctor or other professional healthcare provider without delay.

If you think you are experiencing any medical condition you should seek immediate medical attention from a doctor or other professional healthcare provider.

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