Bipolar disorder: is valproate the right treatment for me?



Valproate is also known as: Sodium valproate, Valproic acid, Epilim, EpilimChrono, Epilim Chronosphere, Episenta, Epival, Convulex, Syonell, Belvo, Orlept, Depakote, Dyzantil, Depakin

What is this document?

This document contains information that will help you understand the potential risks and benefits of valproate and help you decide whether to keep taking it or not. There are other medicines you can take instead of valproate – see pages 3 and 4.

Pages 2 - 5 will help you make a decision

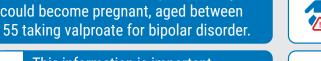
Page 6 explains about contraception and how effective it is



You can work through this document and then talk to your specialist about it.

Why is it important?

This document is for women, girls and anyone who could become pregnant, aged between 12 – 55 taking valproate for bipolar disorder.





This is because if you take valproate and you are pregnant it can seriously harm your baby.



This information is important. Medical advice is that you should not get pregnant when taking valproate.



If you could get pregnant, medical advice is to avoid valproate unless there are no other options and you use a highly effective contraception (see page 6).

If you're taking valproate, there is a high risk of your baby having major birth defects and developmental disorders. These harms can happen at any time in the pregnancy, even when you don't know you're pregnant.

Risk of possible multiple major birth defects (Out of every 100 people)

In general we'd expect 2 – 3 babies to be born with major birth defects. 97 - 98 won't.

On valproate we'd expect 10 - 12 babies to be born with major birth defects. 88 - 90 won't.

Risk of possible multiple developmental disorders (Out of every 100 people)

In general we'd expect 3 babies to be born with developmental disorders. 97 won't.

On valproate we'd expect at least 40 babies to be born with developmental disorders. Fewer than 60 won't be diagnosed with one.

Important

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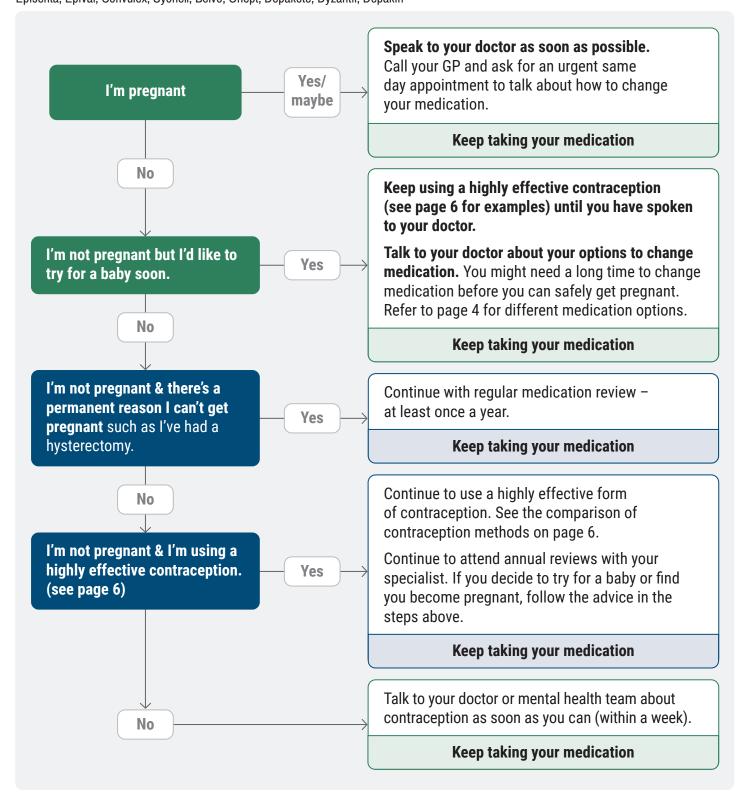
- **Never** stop taking valproate or any other medicine for bipolar disorder before talking to your doctor or community mental health team.
- If you are taking valproate and it is possible you could get pregnant, talk to your psychiatrist, perinatal mental health (PMH) team or your GP.
- If you are currently taking valproate and think you are pregnant, you should call your GP and ask for an emergency appointment.

Tell the receptionist that you need to speak to a doctor that same day, because you are taking valproate and might be pregnant. Don't stop taking valproate until you and your doctor have made a plan. You are not alone - this can be a worrying time but your doctor will support you with what to do next.

There are links on the back page where you can go for support and more information if you're worried or just want to know more.

I'm taking valproate

Valproate is also known as: Sodium valproate, Valproic acid, Epilim, Epilim Chrono, Epilim Chronosphere, Episenta, Epival, Convulex, Syonell, Belvo, Orlept, Depakote, Dyzantil, Depakin



Important

If you haven't had a medication review in the last 12 months

- Book one with your doctor as soon as you can (within 4 weeks)
- ✓ Keep taking your medication
- Keep using a highly effective form of contraception

Potential benefits and harms of valproate and other options

What are the potential benefits?

All medicines have potential benefits and harms. Valproate, lithium and antipsychotics are prescribed to treat bipolar disorder.

Staying on valproate

• There will be no change to your current treatment.

Changing your medicine

- If you are thinking about getting pregnant, different medicines have a much lower risk for the baby.
- Other medicines you can take include antipsychotics (olanzapine, quetiapine, aripiprazole, risperidone), and lithium.
- Valproate, lithium and antipsychotics are used to treat acute episodes of bipolar disorder and also in the long term to prevent relapses.
- We can't say which medicines work better than another because which medicine is best for you is very individual. How well it works and which side effects someone might have will be different for each person. Which is best for you needs to be carefully chosen by you and your psychiatrist together.

Where can I get support?

The specialist perinatal mental health clinic in your area

Bipolar UK

www.bipolaruk.org (Search for Bipolar UK leaflet on Bipolar and Pregnancy)

Mind

https://www.mind.org.uk Phone: 0300 123 3393

Choices

www.contraceptionchoices.org (Search in videos)

Tommy's

https://www.tommys.org/pregnancy-information/search?keys=bipolar

Royal College of Psychiatrists

https://bit.ly/3KLNS0E

Action on post partum psychosis www.app-network.org

BUMPS – Best use of medicines in pregnancy www.medicinesinpregnancy.org

If you want a 2nd Opinion Clinic www.ncmh.info/resources/cups/

Potential benefits and harms of valproate and other options

What are the potential harms to my baby?

All medicines have potential benefits and harms. The numbers here are averages and your specific benefits and risks might be higher or lower than these.

What are the numbers below?

They show the chance of your baby having these problems. They are averages. Your specific risk might be higher or lower. The numbers do not show how severe these problems might be.

What are birth defects?

They include spina bifida, cleft palate, malformed arms and legs, heart, kidneys, urinary tract or sexual organs, hearing problems, deafness and others. Some birth defects are much worse than others. Your doctor will explain these to you. Valproate can cause **more than one defect** in each child.

What are developmental problems?

They include learning to walk and talk later than normal, lower intelligence than children of the same age, poor speech and language skills, memory problems, increased risk of autism or ADHD, behaviour problems that don't always respond to treatment.

These harms can happen at any time in the pregnancy, even those first few weeks before you know you're pregnant.

Risk of possible multiple major birth defects (Out of every 100 people)

In general we'd expect 2 – 3 babies to be born with major birth defects. 97 – 98 won't.

On **valproate** we'd expect **10 – 12** babies to be born with **major birth defects**. **88 – 90** won't.

Risk of possible multiple <u>developmental disorders</u> (Out of every 100 people)

In general we'd expect 3 babies to be born with developmental disorders. 97 won't.

On **valproate** we'd expect **at least 40** babies to be born with **developmental disorders**. Fewer than **60** won't be diagnosed with one.

Alternative medication

If you are taking valproate and it's possible you could get pregnant, make an appointment to discuss your situation with your psychiatrist or Perinatal Mental Health team as soon as you can.

There are other medicines you can take for bipolar disorder that are safer for a developing baby:

Lithium – The risk of developmental problems in the baby are the same as for people not taking lithium. There may be an increased risk of a heart defect in babies when lithium is taken during pregnancy. It is thought that 2 in every 100 babies whose mothers took lithium had a heart defect, compared to 1 in 100 whose mothers did not take lithium.

Antipsychotics (olanzapine, quetiapine, ariprazole, risperidone). The risk of developmental problems or birth defects when these are taken during pregnancy is the same as for people not taking these medicines.

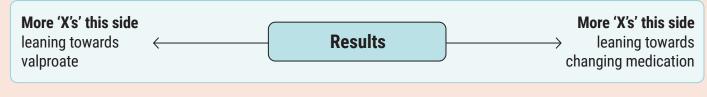
Which alternative medicines are suitable for you will depend on your own situation.

Help to decide what's important to you

Your personal feelings are an important part of making a health decision. Think about what matters most to you in this decision.

On each question, consider your answer, put an 'X' where you feel your answer lies, and check the your results. Then, talk the answers through with your doctor.

Definitely	No st	rong opinion			Definitely
I will not get pregnant		king about ng children			I might like to get pregnant soon
I can manage my contraception	Thinking ab	out contrac	eption		I cannot manage my contraception
Overall, I feel relatively healthy		about gene ell-being	eral	I d	o not feel comfortable or healthy generally
I have tried other medications and they don't work for me	Thinking about y	our medica	tion histor	у	I haven't tried any other medications
I'm worried my mental health might get worse if I change medication	Thinking about	changing m	edication		I'm not worried that my mental health will get worse
Definitely	No st	rong opinion			Definitely



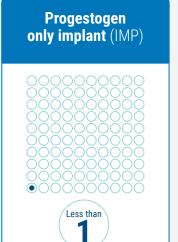
Your doctor will talk to you about staying on valproate or changing medication. Switching to other medicine may be better for bipolar disorder.

How effective is your contraception?

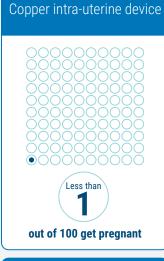
No contraception is 100% effective.

Highly effective means a risk of less than 1 out of every 100 women would get pregnant in a year. Talk to your doctor or healthcare provider about choosing a suitable contraception for you.

How many women, out of every 100, would get pregnant in one year if they used in a typical way:

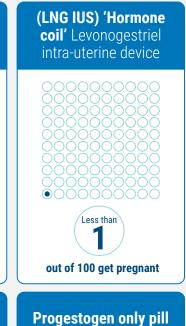


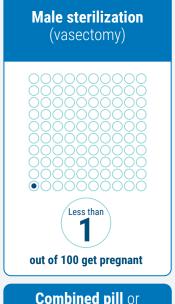
out of 100 get pregnant

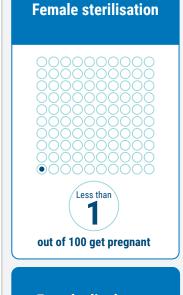


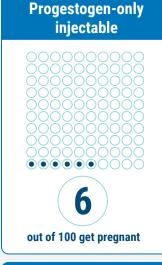
(DMPA/Depo-Provera)

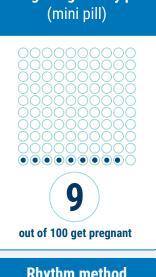
IUD ('the coil')

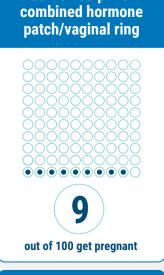


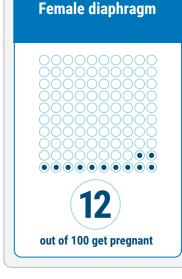


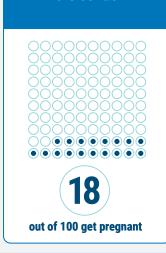




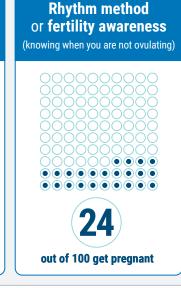


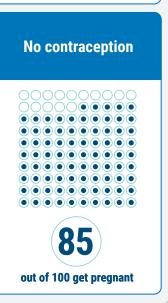






Male condom





Where did we get our numbers from?

Royal College of Psychiatrists position on valproate

https://bit.ly/3jdL1B0

Valproate – pregnancy prevention programme

https://bit.ly/3NN5efL

Valproate and other drug risks

Antiepileptic drugs: review of safety of use during pregnancy – MHRA Public Assessment Report January 2021 https://bit.ly/36YIOaA

Contraception

https://www.nhs.uk/conditions/contraception/how-effective-contraception/

Risk in the general population – Public Health England Report on how many babies are born with birth defects https://bit.ly/3LM3oK3

Risks of developmental disorders from taking antipsychotic medicine, 3.4 million children were followed up for up to 14 years. Almost 10,000 of these were exposed to antipsychotics.

https://doi.org/10.1001/jamainternmed.2022.0375

Risk of lithium to babies in a study of over 1 million pregnancies where 663 children were exposed to lithium https://doi.org/10.1056/NEJMoa1612222)

Risk of developmental problems with lithium, British Association of Psychopharmacology guidelines https://doi.org/10.1177/0269881116636545

Do you feel sure about wh	Yes No		
Do you know the risks and	Yes No		
Are you clear about which	Yes No		
Do you have enough supp	Yes No		
If you answered 'No' to ar	ny of these, talk to your healthcare team about your q	uestions or concerns.	
Questions for y	our specialist	Contraception	
questions for y	car specialist	Contraception	
	ay be in person or on the phone. Use this	What is your current form	
space to write any questic healthcare professional.	ons you might have for your doctor or	of contraception?	
nealtheate bluteccional			
nearmoure professional.			
meaninoure professional.			
meanificate professional.			
neutrioure professional.			
neutrioure professional.			
Treatmoure professional.			
Contacts	Name	Telephone	
Contacts	Name	Telephone	
	Name	Telephone	
Contacts GP Psychiatrist		Telephone	
Contacts		Telephone	
Contacts GP Psychiatrist Community mental health Other		Telephone	
Contacts GP Psychiatrist Community mental health Other	team	Telephone	

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