

A handy fact sheet on valproate in pregnancy and breastfeeding

(this includes sodium valproate, valproic acid, semisodium valproate, divalproex; brand names include Belvo, Convulex, Depakote, Dyzantil, Epilim, Episenta, Epival, and Syonell)

This fact sheet should be read alongside our other Choice and Medication leaflets, which include more information on this medicine and its side effects

Valproate can cause some harm during pregnancy. Strict rules now apply to prescribing it to females (adults or girls) who could get pregnant, and also to men.

What should I do if I am taking valproate and want to start a family?

Valproate must not be prescribed to females of childbearing potential unless they are on the 'Valproate Pregnancy Prevention Programme' (or the Special Pregnancy Prevention Programme in the Republic of Ireland)

Valproate can cause serious birth defects in 1 in 10 children, and 3 – 4 in 10 can have serious development problems e.g. autism, learning disability, possibly ADHD, so its use is restricted.

If you are a female of childbearing potential (i.e. you *could* become pregnant, however unlikely) and are taking valproate, then there are three main options for you:

1. Gradually come off valproate and see how you are without it
2. Switch to another medicine
3. Carry on, but **you must** then be on the valproate Pregnancy Prevention Programme (PPP).

Do not stop your contraception or valproate until you've spoke to your specialist prescriber

What are the rules about prescribing valproate?

These continue to change but at the moment the rules are:

If you are under 55 and already taking valproate:

- Women must be on the Pregnancy Prevention Programme (see below)
- Men must talk to your prescriber about the risks for your fertility.

New starters:

From 2024 (in the UK) valproate can only be started in someone (male or female) aged under 55 if:

- Two specialists agrees and documents that there is no alternative treatment
AND
- Female patients are on the Pregnancy Prevention Programme

Females:

If you could get pregnant ('a woman of childbearing potential'), however unlikely, to take valproate you must:

- Be on the UK "Valproate Pregnancy Prevention Programme" or the Republic of Ireland HPRA's Special Pregnancy Prevention Programme and follow their rules
- Use **highly effective contraception** the whole time that you are taking valproate
- Have an annual review and complete the Risk Acknowledgement Form
- And, if you think you could be pregnant, see your prescriber straight away. They will help you to stop valproate as quickly and as safely as possible.

Men:

- There is a risk that any child of a father who has taken valproate in the last 3 months could have a neurodevelopmental disorder such as autism, learning disability, ADHD, or a movement problem
- Talk to your prescriber about the risks for your fertility.

I am taking valproate and have just found out I am, or think I might be, pregnant. Should I stop my valproate?

- **You must see your prescriber as soon as you can (in the next day) and then see your specialist prescriber**

- **Stopping valproate will be the aim but it must be in a gradual, slow and controlled way as soon as possible**
- **If you are not on the Valproate Pregnancy Prevention Programme then you also need to ask why not**
- Decide on a plan of action together. You may need a little time to look through the information in the rest of this leaflet and make your choices
- The risks of malformation are higher with higher doses e.g. above 1g (1000mg) a day. If you take 3g (3000mg) per day, over 6 in 10 (60%) of babies may have some malformation, but there is no safe dose
- You should be offered a special scan to check for any problems
- The risk of becoming unwell again is greater if you stop taking valproate suddenly
- It is important to take high dose folic acid supplementation (5mg a day) for at least the first 3 months of pregnancy

What are the risks of continuing valproate during early pregnancy?

- **The first trimester (i.e. months 1-3)** is when your baby's organs are developing, and this carries the highest risks.
- Valproate use in pregnancy has been strongly linked to a number of major malformations such as spina bifida and heart problems, as well as many others.
- There may be an increased risk of miscarriage.
- Valproate does not seem to increase the risk of preterm birth or baby being born with a small birth weight.

What about later on in pregnancy?

- The risk from valproate carries on throughout pregnancy, as the baby's brain develops
- Restarting valproate during the second trimester (month 4) onwards should **only** be done in epilepsy if your seizures cannot be managed by *anything* else. There are other much safer options for mood problems in pregnancy.
- Valproate levels have been shown to reduce as pregnancy goes on so you might need to have your dose changed to manage your seizures.

What about delivery time?

- You may be advised to have your baby in hospital so both you and baby can be closely checked.

What about valproate and breastfeeding?

- Valproate shouldn't impact on your ability to breastfeed
- Valproate is considered 'very low risk' in breastfeeding
- Valproate passes into breast milk in small amounts but you can still breastfeed – no short or long term growth or cognitive problems have been seen in babies whose mothers took it
- If your baby is born early (pre-term) or has any health concerns then get advice from a healthcare professional first.
- If you are breastfeeding while taking valproate you **must** be using highly effective contraception (as part of the Valproate Pregnancy prevention programme)
- If your baby becomes restless, very sleepy or develops feeding problems stop breastfeeding and quickly seek medical advice.
- Your baby should be checked for possible side effects such as yellow skin or eyes (jaundice) or unusual bruising

What about later on and baby's development?

- **If you took valproate during pregnancy there could be problems**
- There is a real risk of poor physical and mental development (e.g. being clumsy, lower IQ, memory and communication problems, hearing problems or deafness, autism and ADHD)
- **It is unlikely there will be any long-term effects on the baby if you only took valproate while breastfeeding.**

What else can I do to help myself stay well?

- Talking therapies can be helpful, with or without medicines
- Do **not** take any other medicines that you do not need. Check with your local pharmacist before buying any medicines over the counter
- Eat a healthy balanced diet rich in fruit and vegetables
- Exercise regularly
- Stop or cut down smoking
- Do **not** drink alcohol. Drinking alcohol in

pregnancy can lead to long-term harm to your child. The more you drink, the greater the risk

- Don't ignore feelings of thirst - drink enough water so you don't become dehydrated.
- If you are being sick during your pregnancy then you are more likely to become dehydrated. Drink plenty of water and see your prescriber. There are treatments that can help with the sickness
- Ask your healthcare team if you should be

taking vitamin supplements such as folic acid, iron or vitamin D. **Folic acid is vital and you should be prescribed and take 5mg a day**

- Go for any extra blood tests needed
- If you feel stressed look at non-drug ways to help you relax but do not mix up the effects of being pregnant with symptoms of becoming unwell
- Ensure you have a support network in place, so there is someone who can help you recognise if you are struggling.

You can make your own notes here. Write down any questions you may want to ask your health care team

The small print: This leaflet is to help you understand more about valproate and pregnancy. You **must** also read the manufacturer's Patient Information Leaflet (PIL). Go to our website for fuller answers to many other questions.

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