



## Advice for women and girls taking valproate medicines

24 April 2018

### 1. What are valproate medicines?

Valproate is a chemical name and short-hand for valproic acid. Valproate or valproic acid is combined with sodium or semi-sodium so you may see any of these names on your medications.

The following are brands of valproate medicines: **Epilim**, **Depakote**, Convulex, Episenta, Epival, Kentlim, Syonell, Orlept, and Valpal.

Valproate medicines can be used to help manage epilepsy or bipolar disorder. It is very important you **do not stop taking this medicine until you have talked to your specialist**.

### 2. Why have changes been made to how valproate medicines can be used?

Valproate medicines can seriously harm an unborn baby when taken during pregnancy.

Latest figures suggest that if 100 women take valproate medicines during their pregnancy, about 10 of the babies would be born with physical birth defects (compared with 2 to 3 out of 100 in the general population). And about 30 to 40 of the 100 children would go on to have neurodevelopmental disorders (affecting learning and thinking abilities, including autism).





Valproate has been known for many years to cause birth defects. A 2014 review added the additional risk of neurodevelopmental problems. A recently completed European review recommended **more needs to be done to prevent harm** to babies and children from valproate medicines.

### 3. What does this mean for me?

You and your specialist may decide that valproate is the only treatment that works for you. If so, they will discuss with you the need to **always use effective contraception to prevent you from getting pregnant.**

You can talk to your GP or family planning/sexual health centre about what contraception is right for you. But you should always tell healthcare professionals that you are on valproate medicines when you discuss your options. Depending on what contraception you are using, your GP may discuss the need for pregnancy testing to make sure you haven't become pregnant while you are taking valproate.

Your specialist must invite you for a **review at least every year** to discuss if valproate is still the right treatment for you. In this review, you and your specialist must sign a form to confirm that you understand the risk. If you haven't been invited for a review and you want to discuss your treatment, you can ask your GP to refer you to your specialist.

### 4. What should I do if I think I might be pregnant?

If you think you might be pregnant, talk to your GP, specialist, or specialist nurse straight away. **Do not stop taking valproate until you have talked to your specialist.**



If you think that your baby or child has been born with problems caused by valproate medicines, discuss with your GP, specialist, or specialist nurse. You can also report this directly to the MHRA's Yellow Card Scheme on the [website](#) or on the Yellow Card mobile app.

## 5. What should I do if I want to get pregnant?

Tell your GP, specialist, or specialist nurse **as quickly as possible** if you are planning to become pregnant. It can sometimes take a long time to safely change treatments, so it is important that you **start this discussion early**.

## 6. What should happen when I am prescribed valproate medicines?

When you see your GP, specialist, or specialist nurse they should:

- talk to you about the risk to babies and the need to use effective contraception
- make sure you've seen a specialist in the past year for a review
- offer you the updated patient guide for more information

## 7. What should happen when I receive my valproate medicines?

When you receive your valproate tablets, your pharmacist should:

- make sure there is a warning on the pack
- point you towards the patient card and pack leaflet for more information
- check you've seen your GP or specialist to discuss the importance of not becoming pregnant while taking valproate medicine



## 8. Who can I ask for advice?

Talk to your GP, specialist, or specialist nurse about your treatment and plans to have children.

You may also wish to talk to an epilepsy or bipolar disorder charity:

- Bipolar UK: 0333 323 3880
- Epilepsy Action: 0808 800 5050
- Epilepsy Society: 01494 601 400
- Mind: 0300 123 3393
- Young Epilepsy 01342 831342

The following support groups or networks have been set up by patients to support women who have children affected by valproate during pregnancy:

- FACSaware  
Search #FACSaware online or on social media
- In-FACT/FACSA  
01253 799 161 or search online or social media
- OACS  
07904 200364 or search online or social media

This sheet has been produced by the Medicine and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care, to help healthcare professionals to discuss new advice about valproate medicines with patients, parents, and caregivers. This sheet should be used alongside educational materials available from the MHRA website, epilepsy and bipolar charities, and in hard copy from healthcare professionals and Sanofi.