

### FACTSHEET

# Sodium valproate and pregnancy

This factsheet provides information on **sodium valproate**, a common antiseizure medication (ASM).

This is important information for all women and people of child-bearing age who are prescribed sodium valproate whether planning a family or not.

### Sodium valproate

Sodium valproate is a common, and for many people, a very effective ASM. It is also known by other names such as Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Syonell, Valpal, Belvo and Dyzantil.

Unfortunately, sodium valproate can cause physical and developmental difficulties for babies when taken during pregnancy.

The <u>Medicines and Healthcare products Regulatory Agency (MHRA)</u> is the UK agency who regulates medicines ensuring their safety, quality and effectiveness.

According to the MHRA around 10 per cent of children, who were exposed to sodium valproate in the womb, have been affected by physical birth defects. A further 30-40 per cent of children exposed to this drug in the womb have also experienced neurodevelopmental disorders such as difficulty with walking, talking and memory loss.

There are ways to reduce these risks though. If you currently take sodium valproate, please contact your epilepsy specialist nurse or neurologist who will be able to help.

They can discuss your individual situation and consider ways to reduce these risks, and help you find the best solution for you, your baby and your epilepsy.

### Planning a pregnancy

Planning your pregnancy is crucial if you have epilepsy. If you are thinking of starting a family or having another child, then a first step would be to contact your epilepsy specialist nurse or neurologist. Ask for a meeting to discuss your medication, and to review your seizure control.

Together, you can agree on a course of action which is right for you and your epilepsy, but also ensures any risks to your unborn baby are minimised.

## What happens if I find out I am pregnant while taking sodium valproate?

Many pregnancies are not planned, and if you find out you are pregnant, do not panic. Please seek immediate medical advice from your epilepsy specialist nurse, neurologist, or GP.

Never stop your medication unless advised and supervised by your specialist. Suddenly stopping your ASM could trigger a seizure putting yourself and your unborn baby at risk.

It is important that you get expert medical advice and support from a specialist throughout your pregnancy. They will help you manage your epilepsy and your ASMs throughout your pregnancy.

For some people sodium valproate is the only medication which can control their seizures. If this is the case for you, your specialist may advise you to continue to take sodium valproate during your pregnancy. They should arrange for you to see a specialist in foetal medicine. These are healthcare professionals who care for anyone whose babies are at higher risk of birth problems.

Are there other ASMs to avoid when pregnant?

Sodium Valproate is not the only ASM which can affect an unborn child.

Your epilepsy specialist nurse or neurologist will advise you on the safety of all of your ASM(s), and, if appropriate, may switch you to a different, safer drug before you become pregnant.

You can find more information on various ASMs and relevant risks when taken during pregnancy in the MHRA Public Assessment Report January 2021.

### Sodium valproate works well for me, and I do not wish to have a child

For some women or people of child-bearing age, sodium valproate may be the only drug which controls their seizures. For others, pregnancy may be irrelevant to their individual circumstances.

To reduce the likelihood of an unplanned pregnancy, always discuss contraception with your GP, epilepsy nurse specialist or neurologist on a regular basis.

The MHRA requires women or people of childbearing age (under the age of 55) to sign up to a **pregnancy prevention programme (PPP)** before prescribing sodium valproate. In addition, two specialists will need to agree that this is the most effective medication for you, and that the benefits of taking sodium valproate outweigh any risks.

### The Pregnancy Prevention Programme (PPP)

This programme encourages women and people of childbearing age to use contraceptive methods which are considered highly effective, long acting and reversible. They are known as **LARCs or long acting reversible contraceptives**.

LARCs include the intrauterine device (IUD). They are also referred to as the coil. IUDs are devices inserted into your womb and can provide long acting contraception. These need to be changed every five to ten years depending on the type. For many these are effective contraceptives as they do not interfere with ASMs.

Another LARC is the contraceptive implant. This is placed under your skin and releases hormones into your bloodstream to prevent pregnancy. It lasts for three years. There are other contraceptive options available, and your GP, epilepsy nurse or neurologist can give you more information on this.

As part of the Pregnancy Prevention Programme, your epilepsy team will ask you for a yearly review appointment. During this appointment they will discuss and sign with you a Risk Acknowledgement Form. This is to make sure you fully understand the risks of becoming pregnant while taking sodium valproate.

The signed Risk Acknowledgement form will help your GP and pharmacist to continue to prescribe sodium valproate for you.

### Foetal Anti-convulsant Syndrome (FACS)

Foetal Anti-convulsant Syndrome is a summary term for the many ways sodium valproate, and some other ASMs, can affect a child when exposed to it in the womb.

Children with FACS can have a mixture of mild to more serious symptoms. Some physical symptoms can often be treated. Developmental delay can also result as well as speech and language problems, autistic spectrum disorders and poor motor control.

If you think your child has been affected by sodium valproate, or other medicines, please contact your GP.

Your GP will be able to refer your child to a specialist in children's medicine if this is appropriate.

#### Men and sodium valproate

Recent studies have shown that men or people taking sodium valproate may lead to reduced fertility. There may also be a small risk of neurodevelopmental issues for the baby if sodium valproate was taken before conception. In response to this, the MHRA has now extended prescribing restrictions to men/boys under the age of 55.

Sodium valproate can now only be prescribed to anyone under the age of 55 if two specialists have agreed that this is the only effective medication for you, and that the benefits outweigh any risks.

If you have any concerns, speak to your epilepsy specialist nurse, neurologist or GP.

Never stop your medication unless advised and supervised by your specialist. Suddenly stopping your ASM could trigger a seizure putting yourself at risk.

### Further information and support

Your first point of contact should always be your consultant, epilepsy specialist nurse or GP for medical advice which is relevant to your own situation.

You can also contact our confidential freephone helpline 0808 800 2200 for a general chat and emotional support. We can tell you what your next steps should be and who to contact for medical advice.

For information and support on FACS, check out the following websites:

- <u>INFACT</u> National Valproate campaign provides information, advice and support to anyone who has taken AEDs in pregnancy and is concerned it may have affected their unborn child during pregnancy
- <u>FACSA support group</u> a support group for families and children affected by FACS syndrome

 Organisation for Anti-Convulsant Syndromes (OACS Charity) provides help and support to families affected by the syndrome.

With thanks to Dr Shona Scott, Consultant Neurologist, and Yvonne Leavy, Epilepsy Specialist Nurse (Adults) Edinburgh for their valued input and advice.

Our resources are always free. If you would like to support our work, please text FACTS to 70085 to donate £3. Texts cost £3 plus one standard rate message.



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