

What are the risks for males and females?



Sodium valproate is an effective anti-seizure medication (ASM), and for some people with epilepsy it is the only medication that controls their seizures. Various different forms of sodium valproate are available, including Epilim, Depakote, Convulex, Episenta, Epival, Kentlim, Orlept, Sodium Valproate, Syonell, Valpal, Belvo and Dyzantil. It may also be called 'valproate' or 'valproic acid'.

Research shows that sodium valproate can cause serious problems in a developing baby. Therefore, the Medicines and Healthcare Products Regulatory Agency (MHRA) has advised that it must not be prescribed to girls, or women and men under the age of 55 unless it is the only ASM that works for them.

Women, girls and sodium valproate

If a baby is exposed to sodium valproate during pregnancy, there is a risk of it being born with physical disabilities, sometimes called birth defects, and developmental issues. This applies whether valproate is taken alone or in combination with other medicines.

Of babies whose mothers take sodium valproate during pregnancy, up to 1 in 10 (10%) are at risk of having a birth defect and up to 4 in 10 children (40%) have problems with development and learning as they grow up.

These risks may apply to other ASMs but are higher for sodium valproate than for other ASMs. Birth defects can include:

- 'minor malformations' (such as small fingers and toes); and
- 'major malformations' (such as spina bifida or a cleft palate, which may need surgery).

When sodium valproate is taken during pregnancy, it may also affect a child's development and learning after they are born and as they grow up. Development and learning problems are sometimes known as 'fetal anti-convulsant syndrome'.

Problems can include:

- delayed walking and talking;
- poor speech and language skills;
- memory problems; and
- lower intelligence than other children of the same age.

Children exposed to sodium valproate in the womb are also more likely to have an autism spectrum disorder.

MHRA guidance – women and girls

The MHRA currently recommend that sodium valproate must no longer be prescribed to girls, and women under the age of 55, unless it is the only drug that works for them and unless they are on a pregnancy prevention programme (sometimes called PREVENT). This is because of the risk of birth defects and developmental disorders for an unborn baby.

Where possible anyone already taking sodium valproate should be switched to another treatment.

[Visit **epilepsysociety.org.uk/pregnancy-and-epilepsy**](https://www.epilepsysociety.org.uk/pregnancy-and-epilepsy) and [epilepsysociety.org.uk/are-there-risks-my-baby](https://www.epilepsysociety.org.uk/are-there-risks-my-baby)

Pregnancy prevention programme (PPP)

If, as a woman or girl, you are prescribed sodium valproate:

- Your specialist will discuss the risks of taking sodium valproate with you, and whether or not you are planning to become pregnant. This will help to decide if the PPP is right for you.

Sodium valproate can cause serious problems in a developing baby. The Medicines and Healthcare Products Regulatory Agency (MHRA) has issued regulations on the way it is prescribed to both men and women.

Helpline 01494 601400
Confidential, national call rate.
Information and emotional support.
[Visit **epilepsysociety.org.uk/helpline**](https://www.epilepsysociety.org.uk/helpline)
for opening hours.

- They will explain the risks to an unborn child if the mother takes sodium valproate during pregnancy. (See page 1 for risks of taking sodium valproate during pregnancy).
- Before you start to take sodium valproate, you will need to have pregnancy tests.
- Your specialist will explain the options for highly effective contraception.
- Your specialist will carry out reviews of your treatment at least annually.
- You and your specialist will complete an annual risk acknowledgement form at each review. This confirms that you have been given, and understood, appropriate advice.
- When you get your medication from the pharmacy, the pharmacist should show you the warning on the medication packaging. They should also make sure you have the patient card and leaflet about sodium valproate and check that you have discussed the risks with your doctor.

[Visit gov.uk/guidance/valproate-use-by-women-and-girls](https://www.gov.uk/guidance/valproate-use-by-women-and-girls)

If you are taking sodium valproate

Women and girls taking sodium valproate

Talk to your specialist as soon as possible about the best options for you. **Do not stop taking sodium valproate or any other ASMs unless your specialist has advised you to.**

If you suddenly stop taking your ASM it could cause your seizures to increase, or to become more severe. Seizures could cause more harm for you and your unborn baby than any risks from the drugs themselves.

Pre-conception counselling

If you are planning a family it is important to speak to your specialist as soon as possible to discuss the best form of treatment to keep both you and your baby safe. This is sometimes called preconception counselling, and is essential when taking any ASM but especially so for sodium valproate. **It is important that you do not stop taking your medication, or your contraception.**

If you are not planning a family

It is still important to have highly effective contraception in place to ensure that you do not become pregnant. Your specialist will explain the options for highly effective contraception.

You must have an annual review with your specialist. Depending on the type of contraception you use you may also need to take a regular pregnancy test and sign a risk acknowledgement form.

If you are already pregnant

Do not stop taking your medication but make an appointment to see your doctor immediately to discuss the best form of treatment.

In some circumstances you may not be able to switch to another medication and your doctor will provide you with more information. You will be closely monitored to ensure you have the best seizure control and to check how your baby is developing.

Men, boys and sodium valproate

There are concerns that sodium valproate may affect male fertility. While these concerns have been recognised since 2011, recent research suggests that sodium valproate may affect the amount of sperm a man produces and the movement of the sperm.

This research is based on animal studies which show that sodium valproate can have a harmful effect on the testes of young animals. There may also be an effect across generations. A simple test can check quality and quantity of sperm.

[Visit gov.uk/drug-safety-update/valproate-re-analysis-of-study-on-risks-in-children-of-men-taking-valproate](https://www.gov.uk/drug-safety-update/valproate-re-analysis-of-study-on-risks-in-children-of-men-taking-valproate)

At the end of January 2024, the MHRA advised that no-one under the age of 55 – both men and women should be started on valproate unless two specialists independently agree and document that there is no other safe and effective medication.

MHRA guidance for men and boys

The MHRA have looked at data from research again and this suggests that there may be a small increased risk of neurodevelopmental disorders in children fathered by men taking valproate three months prior to, or at the time of, conception compared with men on other anti-seizure medicines.

[Visit gov.uk/drug-safety-update/valproate-use-in-men-as-a-precaution-men-and-their-partners-should-use-effective-contraception](https://www.gov.uk/drug-safety-update/valproate-use-in-men-as-a-precaution-men-and-their-partners-should-use-effective-contraception)

Every effort is made to ensure that all information is correct at the time of printing. Please note that information is intended for a UK audience. This information is not a substitute for advice from your own doctors. Epilepsy Society is not responsible for any actions taken as a result of using this information.



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The new guidance for males, which has been introduced as a precaution recommends that:

- **You do not stop taking your epilepsy medication without advice from your doctor or specialist.**
- You and your female sexual partner use effective contraception while taking valproate and for at least three months after stopping treatment.
- You do not donate sperm during treatment with valproate and for three months after stopping taking valproate.
- You talk to your doctor or specialist about the risks and options at your next regular review.
- If you are considering planning a family in the next year, discuss with your specialist, the possibility of switching to another epilepsy medication.
- You report any harmful reactions linked to taking valproate through the Yellow Card scheme.
- If you are aged under 55 years, you should not be started on valproate unless your specialist has discussed the risks with you and another specialist has agreed that your condition will not respond to other treatments. Or that the risks do not apply to you.

[Visit \[epilepsysociety.org.uk/news/men-valproate-and-yellowcard.mhra.gov.uk/\]\(https://www.epilepsysociety.org.uk/news/men-valproate-and-yellowcard.mhra.gov.uk/\)](https://www.epilepsysociety.org.uk/news/men-valproate-and-yellowcard.mhra.gov.uk/)

If you are concerned that your child may have problems caused by sodium valproate

Physical or neurodevelopmental problems caused by exposure to sodium valproate in the uterus are known as fetal anti-convulsant syndrome (FACS).

If you are concerned that your child or children may have FACS contact your GP or doctor to discuss the issues. You and your GP will be able to look at the medications you were prescribed and the dose you were taking. This will help you to understand whether this could have affected your children.

There is no simple test that can confirm a diagnosis of FACS and symptoms can vary significantly from baby to baby. Instead a diagnosis may be reached by eliminating other possible causes. This could include genetic testing.

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Your GP will be able to signpost you to your local learning disability team who will be able to identify the right support for your child. If your child is now an adult, your GP will be able to signpost you to the right support. [Visit \[epilepsysociety.org.uk/are-there-risks-my-baby\]\(https://www.epilepsysociety.org.uk/are-there-risks-my-baby\)](https://www.epilepsysociety.org.uk/are-there-risks-my-baby)

If you feel guilty that epilepsy medication may have caused your child's disabilities

Sodium valproate was first licensed for use in the UK in 1974. Its success in controlling seizures led it to be widely prescribed at a time when there were very few treatment options for people with epilepsy.

It was another 20 years before more drugs became available, offering greater choice of medications with fewer side effects.

In the 21st century people with epilepsy have been encouraged to be partners in their healthcare and to decide on the best course of treatment with their doctor. However, this has not always been the case, and you may not have been offered a choice in the past.

INFACTUK and OACS are two organisations that provide information and support to families affected by Fetal anti-convulsant syndrome.

[Visit \[infectuk.com\]\(https://www.infactuk.com\) and \[oacscharity.org\]\(https://www.oacscharity.org\)](https://www.infactuk.com)

If you would like to talk things through, please contact our confidential Helpline (see page 1 for details).

Epilepsy Society is grateful to Dr F J Rugg-Gunn, Consultant Neurologist & Honorary Associate Professor, Clinical Lead, Chalfont Centre for Epilepsy, who reviewed this information.

For a printed copy of this information contact our helpline.

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