

Valproate▼

Patient Guide

This booklet is for you if you are a girl or a woman taking any medicine containing valproate.

It contains key information about the risks of valproate in pregnancy.

This guide was last updated in January 2016

▼ This medicine is subject to additional monitoring.
This will allow quick identification of new safety information.
You can help by reporting any side effects you may get.
See www.mhra.gov.uk/yellowcard for how to report side effects.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

You may find the following support groups helpful if you are looking for information about epilepsy or bipolar disorder:

Bipolar UK

www.bipolaruk.org

0333 323 3880

Epilepsy Action

www.epilepsy.org.uk

0808 800 5050

Epilepsy Society

www.epilepsysociety.org.uk

01494 601 400

MIND

www.mind.org.uk

0300 123 3393

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Introduction

Valproate is an important medicine used to treat epilepsy and bipolar disorder.

This booklet is for girls and women taking any medicine which contains valproate. It contains key information about the risks you should be aware of if your doctor has recommended valproate as the best treatment for you.

Read this booklet along with the leaflet inside the medicine box. It is important that you read the leaflet even if you have been taking valproate for a while because it contains the most up to date information on your medicine.

You might find it helpful to talk about this booklet with your friends and family. Ask your doctor or pharmacist if you have questions.

Keep this booklet. You may need to read it again.

What are the risks of taking valproate during pregnancy?

Risks to your unborn child.

If you take valproate when you are pregnant it can harm your unborn child.

The risks are higher with valproate than with other medicines used to treat epilepsy.

The risks are there whatever dose of valproate you take, and the higher the dose the higher the risk.

The risks are there when valproate is taken alone and when it is taken with other epilepsy medicines.



How could my child be harmed?

Taking valproate whilst pregnant can harm your child in two ways – it can cause birth defects and problems with development and learning.

The next two pages tell you about the problems that your child could have.

Birth defects

Taking valproate whilst pregnant can cause serious birth defects.

In women who take valproate while pregnant, around 10 babies in every 100 will have a birth defect.

In women who don't have epilepsy, 2-3 babies in every 100 will have a birth defect.



Birth defects seen when mothers take valproate during pregnancy include:

- spina bifida (where the bones of the spine do not develop properly)
- facial and skull malformations (including cleft lip and palate, where the upper lip or facial bones are split)
- malformations of the limbs, heart, kidney, urinary tract and sexual organs.

 Ask your doctor about taking folic acid when trying for a baby. Taking folic acid is generally recommended for anyone trying to have a baby as it can reduce the risk of spina bifida in all pregnancies. However, it is unlikely to reduce the risk of birth defects from valproate.

Disorders of development

If you take valproate while you are pregnant, it could affect your child's development as they grow up.

In women who take valproate while pregnant, about 30–40 children in every 100 may have developmental problems. The long-term effects are not known.

The effects on development can include:

- being late in learning to walk and talk
- lower intelligence than other children of the same age
- poor speech and language skills
- memory problems.



Children exposed to valproate in the womb are more likely to have autism or autistic spectrum disorders. There is also some evidence children may be more likely to be at risk of developing symptoms of attention deficit hyperactivity disorder (ADHD).

I am starting treatment with valproate

What does this mean for me?

If you are a woman or girl who is able to become pregnant, your doctor should only treat you with valproate if nothing else works. This is also the case if you are too young to become pregnant, and needs to be confirmed again when you become old enough to start a family.

When you first start valproate your doctor should explain all the known risks and why they feel that valproate is the right medicine for you.

- If you are too young to become pregnant, it is still important that you and your parents know about these risks so you know what to do when you are old enough to have children.
- If you are already old enough to become pregnant, it is important that you always use an effective method of contraception throughout your treatment. This is important to make sure you don't have an unplanned pregnancy.

If you decide you want to start a family, talk to your doctor about this as soon as possible and do not stop your medicine or stop using contraception until you have been able to discuss this with your doctor. You and your doctor should agree a plan to reduce the risks before you start trying for a baby.



Talk to your doctor or family planning clinic for information or advice on contraception.

I am taking valproate and not planning a family

What does this mean for me?

If you are taking valproate and don't plan to have a baby, make sure you **always use an effective method of contraception.**

Talk to your doctor or family planning clinic if you need advice on contraception.



Tell your doctor at once if you think you might be pregnant or if you become pregnant. It is important that you do not stop taking your medication until you have discussed this with your doctor. Stopping your medicine without medical supervision can be dangerous for you and your baby.

I am taking valproate and planning a family

What does this mean for me?

If you are planning a baby, do not stop taking valproate or stop using contraception until you have talked with your doctor.

It is important that you do not become pregnant until you and your doctor have decided what can be done to reduce the risks to you and your baby's health.

Your doctor may need to change your medicine well in advance of you becoming pregnant **to ensure your medical condition is stable.**

When you become pregnant, you will be monitored very closely. This is to make sure your condition is controlled and to check how your baby is developing.



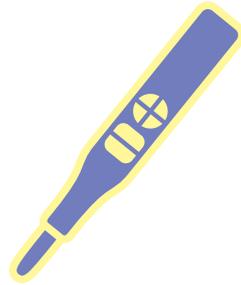
Ask your doctor about taking folic acid when trying for a baby. Taking folic acid is generally recommended for anyone trying to have a baby as it can reduce the risk of spina bifida in all pregnancies. However, it is unlikely to reduce the risk of birth defects from valproate.

I am taking valproate and I've become pregnant

What does this mean for me?

The babies of mothers who take valproate during pregnancy are at a higher risk of birth defects and disorders of development. These can both seriously affect your child's life.

If you are taking valproate and think you might be pregnant or know you are pregnant, contact your doctor at once so that you can talk through your options.



Only stop taking valproate if your doctor tells you to.

Do not stop taking your valproate without speaking to your doctor as your epilepsy or bipolar disorder may become worse.



Ask your doctor about taking folic acid. Taking folic acid is generally recommended for anyone trying to have a baby as it can reduce the risk of spina bifida in all pregnancies. However, it is unlikely to reduce the risk of birth defects from valproate.

Things to remember when taking valproate

- ✓ Valproate is an effective medicine used to treat epilepsy and bipolar disorder.
- ✓ Valproate can seriously harm an unborn child when taken during pregnancy and should be not taken by women and girls unless nothing else works.
- ✓ When taking valproate always use reliable contraception so you do not have an unplanned pregnancy.
- ✓ Speak to your doctor if you are thinking about having a baby and do **not** stop using contraception until you have done so.
- ✓ Tell your doctor at once if you think you may be pregnant or know you are pregnant.
- ✓ Never stop taking valproate unless your doctor tells you to as your condition may become worse.



Thank you for reading this booklet.
Keep it safe as you may need to read it again.