



VALPROATE▼

(Epilim[®], Depakote[®])

Patient Information Booklet

This booklet contains key information about the risks of valproate in pregnancy. This booklet is for you, if you are a girl or a woman taking any medicine containing valproate.

▼ VALPROATE 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 to your doctor/nurse prescriber, pharmacist or nurse and also to the Health Products Regulatory Authority via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2.
Tel: (01) 676 4971. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

VALPROATE

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

Valproate is a medicine which is used to treat epilepsy and bipolar disorder.

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

Keep this booklet as you may need to read it again. Read it along with the package leaflet which comes in the medicine box and if you have any questions, talk to your doctor/nurse prescriber or pharmacist.

What are the risks of taking VALPROATE during PREGNANCY?

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.

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

The next page explains 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.

Birth defects seen when mothers take valproate during pregnancy include:

- spina bifida (when 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.

Developmental disorders

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 to learn 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).

What does this mean for me?

I am starting treatment with valproate

If you are a woman or girl who is able to become pregnant, your doctor/nurse prescriber 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/nurse prescriber 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.

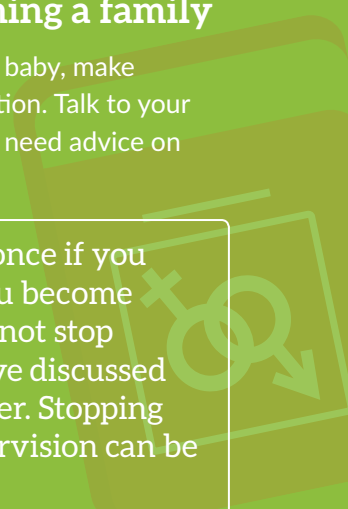
If you decide you want to start a family, talk to your doctor/nurse prescriber about this as soon as possible. Do not stop your medicine or stop using contraception until you have been able to discuss this with your doctor/nurse prescriber. You and your doctor/nurse prescriber should agree a plan to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



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

I am taking valproate and NOT planning a family

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/nurse prescriber or family planning clinic if you need advice on contraception.

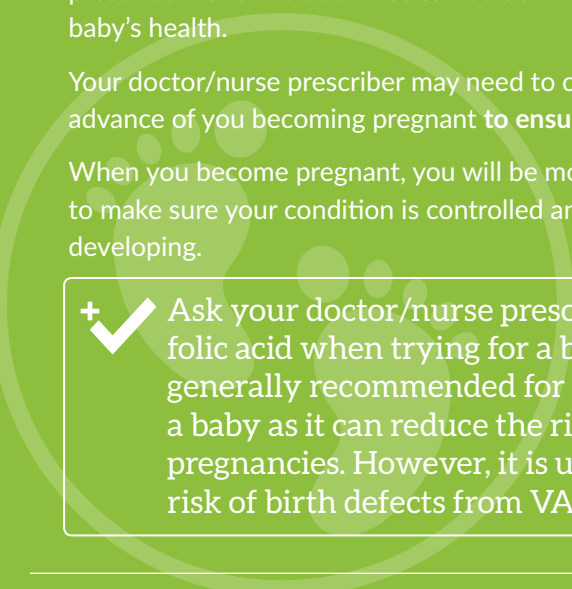
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- + ✓ Tell your doctor/nurse prescriber at once if you think you might be pregnant or if you become pregnant. It is important that you do not stop taking your medication until you have discussed this with your doctor/nurse prescriber. Stopping your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

I am taking valproate and planning a family

If you are planning a baby, DO NOT STOP taking VALPROATE or stop using contraception until you have talked with your doctor/nurse prescriber. It is important that you do not become pregnant until you and your doctor/nurse prescriber have decided what can be done to reduce the risks to you and your baby's health.

Your doctor/nurse prescriber 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.

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- + ✓ Ask your doctor/nurse prescriber 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 have become pregnant

The babies of mothers who take valproate during pregnancy are at a higher risk of birth defects and developmental disorders. 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/nurse prescriber at once so that you can talk through your options.



Only stop taking valproate if your doctor/nurse prescriber tells you to. Do not stop taking valproate without speaking to your doctor/nurse prescriber as your epilepsy or bipolar disorder may become worse.



Ask your doctor/nurse prescriber 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.

It is recommended that pregnancies which occur in women taking valproate **for epilepsy** are enrolled in the Irish epilepsy and pregnancy register, which collects information on the type of epilepsy drugs women are taking while pregnant and on the health of their babies after delivery.

For further information on how you or your doctor can register a pregnancy please see www.epilepsypregnancyregister.ie or Freephone 1800 320 820.

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 not be taken by women and girls unless nothing else works.

When taking valproate always use reliable contraception so you do not have an unplanned pregnancy.

Talk to your doctor/nurse prescriber if you are thinking about having a baby and do NOT stop using contraception until you have done so.

Tell your doctor/nurse prescriber at once if you think you may be pregnant or know you are pregnant.

NEVER stop taking valproate unless your doctor/nurse prescriber 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.

Contact Details for Patient Associations:

Epilepsy Ireland
www.epilepsy.ie (01) 455 7500

AWARE
www.aware.ie 1890 303 302

This guide was published in June 2016.