NEW INFORMATION
JUNE 2026

THIS GUIDE IS FOR GIRLS AND WOMEN WHO CAN BECOME PREGNANT TREATED WITH VALPROATE

VALPROATE▼(EPILIM) PATIENT GUIDE ON CONTRACEPTION AND PREGNANCY

prevent
valproate pregnancy prevention programme

Read this guide along with the leaflet inside the medicine box

VALPROATE (EPILIM)

CONTRACEPTION AND PREGNANCY: WHAT YOU SHOULD KNOW

This guide is for you (or your parent/legal guardian), if you are a girl or a woman who can become pregnant and are taking valproate (Epilim).
It contains key information about the risks of valproate (Epilim) use during pregnancy.
Ask your doctor, nurse, or pharmacist if you have any questions.

Electronic versions of this guide and other materials related to the valproate Pregnancy Prevention Programme can also be found online at **www.hpra.ie**. *Enter "Epilim" or "valproate" in the search box and then click on "EdM" next to any of the medicines that appear.*

KEEP THIS GUIDE. YOU MAY NEED TO READ IT AGAIN.

▼ *This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor, pharmacist or nurse. This will allow for quick identification of new safety information. You can help by reporting any side effects directly via HPRA Pharmacovigilance. Website:* **www.hpra.ie**

THIS GUIDE HAS BEEN APPROVED BY THE HEALTH PRODUCTS REGULATORY AUTHORITY

Purpose of this Guide

This guide is for you (or your parent/legal guardian) if you are a girl, or woman who can become pregnant, taking any medicine containing valproate.

This guide is part of the valproate Pregnancy Prevention Programme, which aims to minimise the risks that could occur through the use of valproate (Epilim) during pregnancy.

- It contains key information about the risks of taking valproate (Epilim) during pregnancy.
- It is important to read this if your doctor has recommended valproate (Epilim) as the best treatment for you, whatever you are taking it for.

Read this guide along with the leaflet inside the medicine box.

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

You might find it helpful to talk about this guide with your partner, friends and family.

- Ask your doctor, nurse or pharmacist if you have any questions.

Chapters 1-3 are relevant for and should be read by all patients who are provided with this Guide.

In Chapter 4-6, please choose and read the situation that applies to you.

You may find the following organisations helpful:

Epilepsy Ireland
Website: www.epilepsy.ie
Email: info@epilepsy.ie
Tel: 01 455 7500

Aware
Website: www.aware.ie
Tel: 1 800 80 48 48

Organisation for Anti-Convulsant Syndrome (OACS)
Website: www.oacsireland.com
Email: info.oacsireland@gmail.com
Tel: 089 219 6011

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PLEASE REFER TO THE LEAFLET INSIDE THE MEDICINE BOX FOR MORE DETAILED INFORMATION

1 Key information to remember

- Valproate (Epilim) is an effective medicine for epilepsy and bipolar disorder.
- Valproate (Epilim) should not be taken by women or girls unless nothing else works.
  This is because valproate (Epilim) can seriously harm an unborn baby when taken during pregnancy.

If you are taking valproate (Epilim) and are able to become pregnant:

- Always use effective contraception (birth control).
- Do not stop using your contraception at any time.

If you are thinking about having a baby:

- First speak to your doctor before stopping your contraception.
- Do not stop taking valproate (Epilim) unless your doctor tells you because your condition may become worse.

If you are taking valproate (Epilim) and have become pregnant:

- Do not stop taking valproate (Epilim) - this is because your epilepsy or bipolar disorder may become worse.
- Talk urgently to your doctor about your options and what you need to know. Your doctor will explain if you need to switch to another treatment and how.

Review your treatment with your specialist regularly - at least once a year.

When you start treatment and during annual visits, you and your specialist will read and sign an Annual Risk Acknowledgement Form. This is to help ensure you know and understand the risks related to the use of valproate (Epilim) during pregnancy and the need to avoid becoming pregnant while taking valproate (Epilim).

2 What are the risks to your baby from taking valproate (Epilim) during pregnancy?

If you take valproate (Epilim) when you are pregnant it can seriously harm your baby in two ways:

- Birth defects when the baby is born.
- Problems with neurodevelopment and learning as the child grows up. The risks are present even with smaller doses of valproate (Epilim).

For the risks of birth defects and neurodevelopment problems, the higher the dose the higher the risks, but all doses carry a risk, including when valproate (Epilim) is used in combination with other medicines used to treat epilepsy or bipolar disorder.

Birth Defects

Taking valproate (Epilim) during pregnancy can cause serious birth defects

- In women who take valproate (Epilim) while pregnant:
  - Around 11 babies in every 100 will have a birth defect.

- In women in the general population:
  - 2 to 3 babies in every 100 will have a birth defect.

What type of birth defects can happen?

Reported birth defects with valproate (Epilim) include for example:

- Malformation of spine bones (spina bifida).
- Face and skull malformations including 'cleft lip' and 'cleft palate'. This is where the upper lip or and bones in the face are split.
- Malformations of the limbs, heart, kidney, urinary tract, sexual organs and of the eyes that may affect vision.
- Hearing problems or deafness.

Neurodevelopment and Learning Problems

Taking valproate (Epilim) while pregnant could affect your child's neurodevelopment as they grow up.

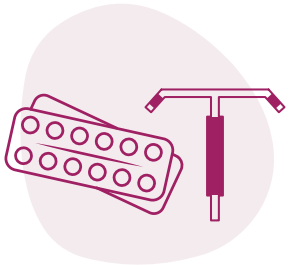
- Up to 30 to 40 pre-school children in every 100 may have problems with neurodevelopment. The following effects on neurodevelopment are known:
  - o Being late in learning to walk and talk.
  - o Lower intelligence than other children of the same age.
  - o Poor speech and language skills.
  - o Memory problems.
- Children are more likely to have autism or autistic spectrum problems and are at increased risk of developing Attention Deficit Hyperactivity Disorder (ADHD).

Birth Weight

If you take valproate (Epilim) during pregnancy, your baby may have a lower weight than expected for their age at birth

- In women who take valproate (Epilim), around 11-15 babies in every 100 may have a lower weight than expected for their age at birth. This compares to 5-10 babies in every 100 born to women from the general population

3 Contraception (birth control)



Always use effective contraception (birth control) recommended by your doctor for the whole time you are taking valproate (Epilim).

This is to prevent you getting pregnant on valproate (Epilim) since it can harm your baby.

Please discuss with your doctor the best method of contraception for you.

Contraception must be used even if you are not currently sexually active, unless there are compelling reasons for assuming there is no risk of pregnancy. Your specialist will discuss this with you.

4 I am an adult, what does this mean for me?

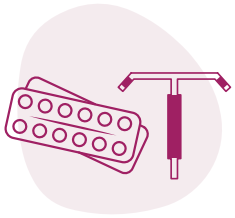
"I AM STARTING TREATMENT WITH VALPROATE (EPILIM)"

Your specialist will explain to you why valproate (Epilim) is the right medicine for you and all the known risks. Your specialist should only treat you with valproate (Epilim) if nothing else works.

- You should only be treated with valproate (Epilim) if you are not pregnant and you are using effective contraception (birth control).
- Your specialist will ask you to perform a pregnancy test before starting valproate (Epilim), and may ask you to repeat this at intervals during treatment. This is to make sure you are not pregnant.
- It is important that you always use effective contraception at all times during treatment with valproate (Epilim). This is to make sure you do not become pregnant.
- You will need to review your treatment with your specialist regularly – at least once a year.

When starting your treatment and during the annual visit, you and your specialist will read and sign an Annual Risk Acknowledgement Form. This is to help ensure you know and understand the risks related to the use of valproate (Epilim) during pregnancy and the need to avoid becoming pregnant while taking valproate (Epilim).

"I AM TAKING VALPROATE (EPILIM) AND NOT PLANNING TO HAVE A BABY"



Always use effective contraception (birth control), even if you are not currently sexually active:

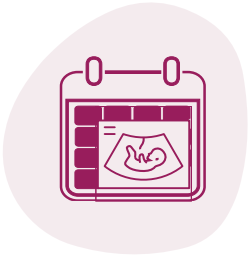
- **Use contraception for the whole time you are taking valproate (Epilim).**
- **Do not stop using the contraception at any time.**

Talk to your doctor or professional at the family planning clinic or nurse for advice on the best method(s) of contraception for you.

Tell your doctor immediately if you are pregnant or think you might be pregnant. Do not stop taking valproate (Epilim) until you have discussed this with your doctor.

Review your treatment with your specialist regularly - at least once a year. During the annual visit you and your specialist will read and sign an Annual Risk Acknowledgement Form. This is to help ensure you know and understand the risks related to the use of valproate (Epilim) during pregnancy and the need to avoid becoming pregnant while taking valproate (Epilim).

"I AM TAKING VALPROATE (EPILIM) AND PLANNING TO HAVE A BABY"



Do not stop using your contraception (birth control) or taking valproate (Epilim). Talk with your doctor first.

- It is important that you do not become pregnant until you have discussed your options with your specialist.
- Your specialist may need to change your valproate (Epilim) treatment a long time before you become pregnant - this is to make sure your condition is stable.

During this visit you and your specialist will read and sign an Annual Risk Acknowledgement Form. This is to help ensure you know and understand the risks related to the use of valproate (Epilim) during pregnancy and the need to avoid becoming pregnant while taking valproate (Epilim).

Valproate (Epilim) can harm babies even in early pregnancy. It is therefore important that you do not delay seeing your specialist if you think you may be pregnant.

"I AM TAKING VALPROATE (EPILIM) AND I THINK I MAY BE OR I AM PREGNANT"

Do not stop taking valproate (Epilim) - this is because your epilepsy or bipolar disorder may become worse.

First talk urgently to your specialist.
If needed, contact your GP to refer you for an urgent specialist appointment.
Your specialist will talk to you about your options and what you need to know.
Your specialist will explain if you need to switch to another treatment and how.

The babies of mothers who take valproate (Epilim) during pregnancy are at a higher risk of:

- Birth defects and
- Neurodevelopment and learning problems.

These can both seriously affect your child's life.

You will be monitored very closely:

- This is to make sure your condition is controlled.
- It is also to check how your baby is developing.

During this visit to the specialist, you and your specialist will read and sign an Annual Risk Acknowledgement Form. This is to help ensure you know and understand the risks related to the use of valproate (Epilim) during pregnancy.

5 I am a parent/legal guardian of a girl, what does this mean for me and my child?

Valproate (Epilim) can seriously harm an unborn baby when taken during pregnancy.

It is important that you and your child understand the risks associated with valproate (Epilim) when used during pregnancy, especially as she grows into adolescence. The specialist will explain these risks to you.

The specialist will explain why valproate (Epilim) is the right medicine to treat your child's epilepsy.

The specialist should only treat your child with valproate (Epilim) if nothing else works.

It's important that your child does not stop taking valproate (Epilim) before talking to her specialist, this is because her epilepsy may become worse.

When your child has her first period, it is important that you contact your child's specialist. If needed contact your child's GP to refer you to the specialist.

During this visit the specialist will:

- reassess treatment with valproate (Epilim) and evaluate alternative treatment options.
- explain the risks to a baby from taking valproate (Epilim) during pregnancy.
- discuss the need for birth control to prevent pregnancy while taking valproate (Epilim).
- discuss the need for pregnancy testing when relevant because valproate (Epilim) should not be taken during pregnancy.
- complete an Annual Risk Acknowledgement Form with you/your child (when she is old enough) to ensure you know and understand the risks to a baby from taking valproate (Epilim) during pregnancy and the need to avoid becoming pregnant while taking valproate (Epilim).

Annual Review

- Once your child has had her first period, she will need to review her treatment with her specialist at least once a year.
- During this visit, you/your child (when she is old enough) will be asked to complete an Annual Risk Acknowledgement Form to ensure you know and understand the risks to a baby from taking valproate (Epilim) during pregnancy and the need to avoid becoming pregnant while taking valproate (Epilim).

The information in this Patient Guide can be shared with your child, in particular as she grows into adolescence. See also Section 6, I am a girl, what does this mean for me?

6 I am a girl, what does this mean for me?

You have been given valproate (Epilim) for your epilepsy and it is an important medicine that keeps you well.

Babies from mothers treated with valproate (Epilim) can have very severe health problems.

Your specialist will talk to you about these recommendations that you need to follow, depending on your circumstances.

I have not yet started my periods

As soon as you have had your first periods, tell your parents/legal guardians.

You will have to see your specialist to review your treatment with valproate (Epilim) at least once a year.

I have started my periods

Before starting treatment with valproate (Epilim), your specialist will check that you are not pregnant.

Your specialist will discuss birth control medicine with you.

It is important to make sure you do not become pregnant while taking valproate (Epilim).

I might be or I am pregnant

Talk straight away to your doctor.

Your doctor will tell you what to do.

Do not stop taking valproate (Epilim) without talking to your doctor. This is because your epilepsy may become worse.

Once you have had your first periods, you will need to see your specialist at least once a year.

During this visit your specialist will:

- check that valproate (Epilim) is still the right medicine for you,
- talk to you about the risks of valproate (Epilim) when used during pregnancy and,
- ask you (when you are old enough) or your parents/legal guardians to sign a form to ensure you know and understand all these recommendations.

In any case, if you have any questions, please ask your doctor or your parents/legal guardians

Never stop taking valproate (Epilim) without talking to your doctor.

NOTES

Thank you for reading this guide.
Keep it safe as you may need to read it again.
Approved by the HPRA.

Electronic versions of this guide and other materials related to the valproate Pregnancy Prevention Programme can also be found online at **www.hpra.ie.** Enter "Epilim" or "valproate" in the search box and then click on "EdM" next to any of the medicines that appear.

For further copies of this guide please contact Sanofi medical information department on

01 403 5600 or email **IEmedinfo@sanofi.com**

qr.epilimandme.ie

Other sources of information:
For the most up to date patient information and important safety information on valproate (Epilim) scan the QR code with a smartphone

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

▼ *This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor. This will allow for quick identification of new safety information. You can help by reporting any side effects directly via HPRA Pharmacovigilance. Website:* **www.hpra.ie**.