

Valproate ▼ (Epilim)

prevent
valproate pregnancy
prevention programme

NEW INFORMATION
– FEBRUARY 2022

Patient Guide for Women and Girls

This booklet is for you (or your parent/legal guardian) if you are a girl (of any age) or a woman of childbearing potential taking any medicine containing valproate (Epilim).

It is part of the valproate Pregnancy Prevention Programme, which aims to minimise the risks that could occur through the use of valproate during pregnancy.

Valproate (Epilim) can seriously harm an unborn baby. Always use effective contraception during your treatment. If you are thinking about becoming pregnant, or you become pregnant, talk to your GP straight away.

Do not stop taking valproate (Epilim) unless your doctor tells you to.

Electronic versions of this booklet and other materials related to the valproate Pregnancy Prevention Programme can also be found online at www.medicinesauthority.gov.mt/rmm. Enter “Epilim” in the search box and find them under PDF Documents

Please keep this booklet. You may need to read it again.

▼ This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor.

This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Report any side effects to postlicensing.medicinesauthority@gov.mt or at www.medicinesauthority.gov.mt/adrportal

This booklet is for women of childbearing potential and girls taking any medicine which contains valproate (Epilim) (or their parent/legal guardian).

- 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 booklet 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 booklet with your partner, friends and family.

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

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

Caritas Malta Epilepsy
Association
www.caritasmalta.org/cmea/

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Contraception for girls and women who are able to become pregnant

Why do I need to use contraception?

This is to stop you getting pregnant on valproate (Epilim).

When taking valproate always use effective contraception that has been recommended by your doctor, at all times during your treatment with valproate.

Contraception must be used even if you are not currently sexually active, unless in your doctor's opinion there are compelling reasons for assuming there is no risk of pregnancy.



What type of contraception should I use?

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

The most effective contraceptive methods include contraceptive injections, implants, and intrauterine devices with copper or hormone.

What are the risks of taking valproate (Epilim) during pregnancy?

Risks to your unborn baby.

If you take valproate (Epilim) when you are pregnant it can seriously harm your unborn baby.

- The risks are higher with valproate than with other medicines for epilepsy or bipolar disorder
- The risks are present even with smaller doses of valproate – the higher the dose, the higher the risks, but all doses carry a risk, including when valproate is used in combination with other medicines used to treat epilepsy or bipolar disorder.



How could my baby be harmed?

Taking valproate whilst pregnant can harm your child in two ways:

- Birth defects when the baby is born
- Physical and mental development problems of the child as it grows after birth.

Birth defects

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

In women who take valproate while pregnant:

- Around 11 babies in every 100 will have a birth defect.

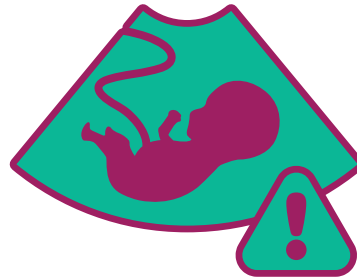
In women in the general population:

- 2 to 3 babies in every 100 will have a birth defect.

What type of birth defects can happen?

- The most frequently reported include:
 - Spina bifida – where the bones of the spine do not develop properly.
 - 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 and sexual organs, and multiple associated malformations affecting several organs and parts of the body.
 - Those birth defects may result in disabilities which may be severe.
- Hearing problems or deafness.
- Eye malformations in association with congenital malformations. These eye malformations may affect vision.

Taking folic acid is generally recommended for anyone trying to have a baby as it can reduce the risk of spina bifida that exists with all pregnancies. However, it is unlikely to reduce the risk of birth defects associated with valproate use.



Physical and mental development problems

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

In women who take valproate while pregnant:

- Up to 30–40 children in every 100 may have problems with development.

The following effects on development are known:

- 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 of mothers who take valproate in pregnancy are more likely to have autism or autistic spectrum problems and are at increased risk of developing attention deficit hyperactivity disorder (ADHD).

I am starting treatment with valproate (Epilim)

What does this mean for me?

Your specialist will explain to you why they feel valproate is the right medicine for you and tell you about the known risks:

- If you are **too young to become pregnant**:
 - Your doctor should only treat you with valproate if nothing else works.
 - It is important that you and your parents/legal guardians know about these risks of valproate when used during pregnancy. This is so you know what to do when you are old enough to have children.
 - You or your parents/legal guardians should contact the specialist as soon as you start your periods during valproate use to have your treatment reviewed and to discuss starting to use effective contraception.
- If you are already **old enough to become pregnant**:
 - Your doctor should only treat you with valproate if nothing else works.
 - Your doctor should only treat you with valproate if you are not pregnant and you are using contraception.
 - Your specialist will ask you to perform a pregnancy test before starting valproate, and may ask you to repeat this at intervals whilst treatment continues. 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. This is to make sure you do not become pregnant.
 - You will need to review your treatment with your specialist regularly (at least each year).
 - At the initial visit your specialist will ask you to read and sign an Annual Risk Acknowledgement Form: this is to make sure you are well aware of and have understood all the risks related to the use of valproate during pregnancy and the need to avoid becoming pregnant while taking valproate.

- If you decide **you want to plan to become pregnant**, talk to your doctor about this as soon as possible
 - Do not stop taking valproate or using contraception – until you have been able to discuss this with your doctor.
 - You and your specialist should agree on what to do with your treatment before you start trying for a baby.

I am taking valproate (Epilim) and not planning a family

What does this mean for me?

If you are taking valproate and do not plan to have a baby, you must use an effective contraception method at all times during your treatment.

Talk to your specialist or gynaecologist/obstetrician or midwife/professional at the family planning/sexual health clinic for advice on the method of contraception.

Consult your GP at once if you think you are pregnant.

Do not stop taking valproate until you have discussed this with your doctor even if you have become pregnant.

You will need to review your treatment with your specialist regularly (at least each year).

During the annual visit your specialist will ask you to read and sign a Risk Acknowledgement Form: this is to make sure you are well aware of and have understood all the risks related to the use of valproate during pregnancy and the need to avoid becoming pregnant while taking valproate.

I am taking valproate (Epilim) and planning a family

What does this mean for me?

If you are planning a baby, first talk to your GP but:

- Keep taking valproate
- Keep using contraception until you have talked with your doctor.

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 medicine a long time before you become pregnant – this is to make sure your condition is stable.
- Valproate can harm babies even in early pregnancy. It is therefore important that you do not delay seeing your GP if you think you may be pregnant.



I am taking valproate (Epilim) and I think I may be or I am pregnant

What does this mean for me?

Do not stop taking valproate – this is because your epilepsy or bipolar disorder may become worse.

First talk urgently to your GP. This is so that you can talk about your options. Your specialist may tell you that you need to switch to another treatment and will explain how to make the change from valproate to this new treatment.

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

- birth defects and
- physical and mental development problems of the child as it grows after birth

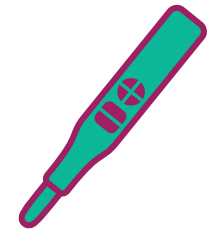
These can both seriously affect your child's life.

In some circumstances, it may not be possible to switch to another treatment. Please refer to your specialist for additional information.

During this visit your specialist will ask you to read and sign a Risk Acknowledgement Form: this is to make sure you are well aware of and have understood all the risks and recommendations related to the use of valproate during pregnancy.


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.
- It is recommended that pregnant women taking valproate are enrolled in the Irish Epilepsy and Pregnancy Register (www.epilepsypregnancyregister.ie).



Key information to remember

- ✓ Valproate (Epilim) is an effective medicine for epilepsy and bipolar disorder.
- ✓ Valproate can **seriously harm an unborn child** when taken during pregnancy – it should not be taken by women and girls unless nothing else works. Whatever your condition never stop taking valproate before discussing with your doctor first.
- ✓ When taking valproate **always use effective contraception** that has been recommended by your doctor at all times during your treatment – so that you do not have an unplanned pregnancy.
- ✓ Make an urgent appointment with your GP if you think you are pregnant.
- ✓ Consult your doctor if you are thinking about having a baby and do not stop using contraception until you have done so.
- ✓ Never stop taking valproate before discussing with your doctor first because your condition may become worse.
- ✓ Remember to visit your specialist regularly – at least once a year.
- ✓ During this visit both yourself and your specialist will discuss and sign an Annual Risk Acknowledgement Form to ensure you are well aware of and understand the risks of valproate use during pregnancy.

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

Approved by the **MEDICINES AUTHORITY**.

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For further copies of this booklet please contact Sanofi Medical Information department at Informazioni.medicoscientifiche@sanofi.com

This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. Report any side effects to postlicensing.medicinesauthority@gov.mt or at www.medicinesauthority.gov.mt/adrportal Adverse events can also be reported to Sanofi Pharmacovigilance and Safety department at PharmacovigilanceMalta@sanofi.com