

Patient Guide

Valproate* Contraception and pregnancy: what you should know

Patient Guide

This booklet is for you if you are a girl or a woman taking any medicine containing valproate, or your caregiver/legal representative.

It is a risk minimization measure part of the valproate Pregnancy Prevention Program aiming to minimize pregnancy exposure during treatment with valproate.

It contains key information about the risk of valproate use during pregnancy.

Information about the use of valproate in women of child-bearing potential and risks of valproate use during pregnancy can also be found online at <https://www.sanofi-pacifico-caribe.com/>

This booklet is for girls and women of childbearing age taking any medicine which contains valproate*, or their caregiver/legal representative.

- It contains key information about the risks of taking valproate during pregnancy.
- It is important to read this if your doctor has recommended valproate as the best treatment for you.
- The type of risks of using valproate during pregnancy is the same for all girls and women using valproate.

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.
- 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, or pharmacist if you have any questions.

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

*Valproate also known as Epilim®, Valpakine®, Depakine®

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1- KEY INFORMATION TO REMEMBER

- Valproate* is an effective medicine for epilepsy.
- Valproate should only be taken by women or girls unless nothing else works. This is because valproate can seriously harm an unborn child when taken during pregnancy. Whatever your illness, never stop taking valproate unless your doctor tells you to do so.
- Always use effective contraception when taking valproate
 - Use contraception for the whole time you are taking valproate
 - Do not stop using the contraception at any timeYour doctor will recommend effective contraception for you.
This is to stop you having an unplanned pregnancy.
- Schedule an urgent appointment with your doctor if you think you are pregnant.
- Consult your doctor promptly if you are thinking about having a baby and do not stop using contraception until you have done so.
- Never stop taking valproate unless your doctor tells you because your illness may become worse.
- Remember to visit your specialist regularly- at least annually.
- During this visit both yourself and your doctor will discuss and sign a Risk Acknowledgement Form to ensure you are well aware of and understand the risks of valproate use during pregnancy.

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2. CONTRACEPTION FOR FEMALE ADOLESCENTS AND WOMEN WHO ARE ABLE TO BECOME PREGNANT

Why do I need to use contraception?

Always use effective contraception when taking valproate*:

- Use contraception for the whole time you are taking valproate
- Do not stop using the contraception at any time

Your doctor will recommend effective contraception for you.

This is to stop you having an unplanned pregnancy.

What type of contraception should I use?

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

Please refer to your doctor, gynaecologist/obstetrician, or midwife for complete counselling.

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3. WHAT ARE THE RISKS OF TAKING VALPROATE* DURING PREGNANCY?

Risks to your unborn child

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

- The risks are higher with valproate than with other medicines for epilepsy
- 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 to treat epilepsy

How could my child be harmed?

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

- Birth defects when the child is born
- Physical and mental development problems of the child as he or she grows after birth.

4. BIRTH DEFECTS

Taking valproate during pregnancy can cause serious birth defects.

In women in the general population:

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

In women who take valproate while pregnant:

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

What type of birth defects can happen?

- The most frequently reported:
 - 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 other congenital malformations. These eye malformations may affect vision.

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5. PHYSICAL AND MENTAL DEVELOPMENT PROBLEMS

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

In women who take valproate while pregnant:

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

The long-term effects are not known.

The following effects on development could be observed:

- 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 increasing risk of developing Attention Deficit and/or Hyperactivity Disorder.

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6. WHAT DOES THIS MEAN FOR ME?

Please choose and read the situations which apply to you from the situations described below:

- I am starting treatment with valproate*.
- I am taking valproate* and not planning a family.
- I am taking valproate* and planning a family.
- I am taking valproate* and I have become pregnant.

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I am starting treatment with valproate*

Your doctor will explain you why they feel valproate is the right medicine for you and tell you about all 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/caregiver 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/caregivers should contact the specialist once you experience menarche during valproate use.

- If you are already **old enough to become pregnant**:
 - Your doctor should only treat you with valproate if you are not pregnant and you are using contraception.
 - Your doctor will ask you to perform a pregnancy test before starting valproate, or thereafter if needed. This is to make sure you are not pregnant.
 - Always use effective contraception when taking valproate:
 - Use contraception for the whole time you are taking valproate
 - Do not stop using the contraception at any time.
 Your doctor will recommend effective contraception for you.
 This is to make sure you do not become pregnant.
 - You will need to review your treatment with your doctor regularly, (at least each year).
- At this initial visit your doctor will ask you to read and sign an Annual Risk Acknowledgement Form: this is to make sure you are well aware and have understood all the risks related to the use of valproate during pregnancy and recommendations to avoid you may become pregnant while taking valproate.
- If you decide **you want to start a family**, talk to your doctor about this as soon as possible
 - Do not stop valproate or using contraception - until you have been able to discuss this with your doctor.
 - You need to talk to your doctor about the risks for your baby's health while keeping your illness under control.
 - You and your doctor should agree on what to do with your treatment before you start trying for a baby.

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I am taking valproate* and not planning a family

Always use effective contraception if you are taking valproate and do not plan to have a baby.

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

Talk to your doctor or gynaecologist/obstetrician or midwife/professional at the family planning clinic if you need advice on the method of contraception.

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

Never stop taking valproate until you have discussed this with your doctor even in case you have become pregnant as it can be dangerous for you and your baby.

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

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

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I am taking valproate* and planning a family

If you are planning a baby, first talk to your doctor 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 and your doctor have talked.

- Your doctor may need to change your medicine a long time before you become pregnant – this is to make sure your illness is stable.
- You need to talk about what can be done to reduce the risks for your baby's health while keeping your illness under control.
- Ask your doctor about taking folic acid when planning to have a baby. Folic acid can lower the general risk of spina bifida and early miscarriage that exists with all pregnancies. However, it is unlikely that it will reduce the risk of birth defects associated with valproate use.

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

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

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I am taking valproate* and I have become pregnant

If you think you may be pregnant:

Do not stop taking valproate - this is because your epilepsy may become worse.

Talk promptly to your doctor. This is so that you can talk about your options. Your doctor may tell that you may need to switch to another treatment and will explain how to make the transition 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 always be possible to switch to another treatment. Please refer to your doctor for additional information.

During this visit your doctor will ask you to read and sign a Risk Acknowledgement Form: this is to make sure you are well aware 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 illness is controlled.
- It is also to check how your baby is developing.

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This material is part of the risk minimization plan, applies only to patients prescribed with this medication and will be delivered directly by prescribing physician.

For more information, contact the medical department:
In Bolivia, Central America and Caribbean countries:

Sanofi-Aventis de Panamá S.A. Torre Evolution, piso 32, Calle 50 y Av. Aquilino de la Guardia Obarrio- Ciudad de Panamá, República de Panamá Telf.: (507) 382-9500.

Web site: <https://www.sanofi-pacifico-caribe.com/es/profesionales-de-la-salud>

For reports of adverse events in the Caribbean and Central America countries: drugs.camwi@sanofi.com

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