

Patient Guide

Valproate (Orfiril, Orfiril long and Orfiril retard)

Important information on the use of valproate and the risk of serious harm to the unborn child during pregnancy

Patient Guide

This booklet is for girls and women (or their parents/guardian) who take medicines that contain valproate.

This booklet contains important information about taking valproate during pregnancy and the risk of harm to the unborn child. The intent is to urge women to prevent pregnancy while being treated with valproate. The risk of using valproate during pregnancy is the same for all girls and women taking this medicine.

Read this booklet, as well as the package leaflet and patient card that came with the medicine package.

- It is important that you read this Patient Guide, even if you have been using valproate for a while, as this guide contains the most recent information about the medicine.

You may find it helpful to discuss this booklet with your spouse or partner, family and friends.

- Contact your doctor, a midwife or a pharmacist if you have any questions.

Keep this booklet in case you need to read the information again.

Information on the use of valproate in women of childbearing potential and the risk of using valproate during pregnancy can also be found online at Felleskatalogen.no

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 - I am taking valproate and plan to become pregnant
 - I am taking valproate and am pregnant

1. IMPORTANT INFORMATION TO REMEMBER

- Valproate is used in the treatment of epilepsy and bipolar disorder.
- Valproate taken during pregnancy can cause serious harm to the unborn child. It should not be used by girls or women unless there is no other adequate treatment.
- As long as you are taking valproate, you must always use effective contraception as recommended by your doctor, without interruption, during the entire treatment period to prevent unplanned pregnancy.
- If you think you may be pregnant, schedule an appointment with your doctor as soon as possible.
- If you plan to become pregnant, do not stop using contraception until you have talked to your doctor.
- Do not stop taking valproate unless your doctor advises you to, as your condition may worsen.
- Remember to keep regular appointments with a specialist, at least once a year.

During your appointment, you and the specialist will review a risk acknowledgement form that provides information on the risk of harm to an unborn child. This is to make sure that you understand the risks involved when taking valproate during pregnancy.

2. CONTRACEPTION FOR GIRLS AND WOMEN WHO COULD BECOME PREGNANT

Why should I use contraception?

When taking valproate, you must always use effective contraception as recommended by your doctor, without interruption and during the entire period of treatment to prevent pregnancy.

What type of contraception should I use?

Ask your doctor about the best type of contraceptive method for you.

Talk to your doctor, a gynaecologist/obstetrician or a midwife for more detailed advice.

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

Risks to the unborn child

If you take valproate while pregnant, it can seriously harm your unborn child.

- These 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 risk.

How could my baby be harmed?

Taking valproate during pregnancy can harm your child in two ways:

- Birth defects.
- Developmental problems and learning disabilities

4. BIRTH DEFECTS

Using valproate during pregnancy can cause serious birth defects

For women in general, around 2 to 3 infants in every 100 will be born with birth defects.

For women who take valproate during pregnancy, around 10 infants in every 100 will have birth defects.

What type of birth defects may occur?

- Spina bifida – a developmental disorder of the spine, where one or more vertebrae of the spine do not develop properly.
- Malformations of the face and skull – such as cleft lip and cleft palate. This is where the upper lip and/or bones of the face are split.
- Malformations of the limbs, heart, kidney, urinary tract and sexual organs.
- Hearing problems or deafness.

5. DEVELOPMENTAL PROBLEMS AND LEARNING DISABILITIES

The use of valproate during pregnancy can affect your child's development and learning abilities.

Up to 30–40 in every 100 children who are exposed to valproate before birth will have developmental problems. The long-term effects of these are unknown.

The following known effects on development include:

- Delayed milestones such as late language and walking.
- Lower intelligence than other children of the same age.
- Poor speech and language skills.
- Memory problems.

Children of mothers who took valproate during pregnancy are at higher risk of autism or autism spectrum disorders. They are also at a higher risk of developing attention deficient and hyperactivity disorders (ADHD).

6. WHAT DOES THIS MEAN FOR ME?

Read more about the situation that applies to you below:

- I am starting treatment with valproate.
- I am taking valproate and have no plans to become pregnant.
- I am taking valproate and plan to become pregnant.
- I am taking valproate and am pregnant.

I am starting treatment with valproate

Your doctor will explain why they believe that valproate is the right medicine for you and inform you of 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/guardians are aware of the risks of using valproate during pregnancy. This is so you know what to do when you are old enough to have children.
 - You or your parents/guardians must contact a specialist as soon as you have your first menstrual period while using valproate.
- 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 take a pregnancy test before starting you on valproate, and repeat this later if necessary. This is to make sure that you are not pregnant.
 - Always use effective contraception without interruption during your treatment with valproate. This is to make sure you do not become pregnant.
 - You and your doctor must assess your treatment regularly (at least once a year).
 - At your first appointment with your doctor, you will be asked to read a risk acknowledge form that explains the risk of harm to an unborn child. This is to make sure you know the risks of using valproate during pregnancy, and that you are informed of and understand the recommendation to prevent pregnancy while using valproate.
- If you decide **you want to become pregnant**, you must talk to your doctor as soon as possible.
 - Do not stop using valproate or contraception before you have discussed this with your doctor.
 - Talk to your doctor about the risks to the child's health and how to keep your condition stable.

- You and your doctor must agree on future treatment before you try to become pregnant.

I am taking valproate and have no plans to become pregnant

If you use valproate and do not plan to become pregnant, you must use an effective contraception at all times during your treatment period, without interruption.

Talk to your doctor, gynaecologist/obstetrician or midwife/public health nurse if you need advice on your method of contraception.

If you think you are pregnant, contact your doctor as soon as possible.

Do not stop taking valproate until you have discussed this with your doctor, even if you are pregnant, as this may be harmful to both you and your child.

You and your doctor must assess your treatment regularly (at least once a year).

At your annual appointment with your doctor, you will be asked to read a risk acknowledge form that explains the risk of birth defects. This is to make sure that you are informed and understand the risk of using valproate while pregnant, and that you are informed and understand the recommendation to prevent pregnancy when using valproate.

I am taking valproate and plan to become pregnant

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

- **keep taking valproate**
- **keep using contraception until you have spoken with your doctor**

It is important that you do not become pregnant until you have discussed your options with your doctor.

- Your doctor may need to change your medicine long before you become pregnant. This is to make sure that your condition remains stable.
- You must discuss what can be done to reduce the risks to your child's health while also ensuring that your condition remains stable.

You and your doctor must assess your treatment regularly (at least once a year).

At your appointment with your doctor, you will be asked to read a risk acknowledge form that explains the risk of birth defects. This is to make sure that you are informed and understand the risk of using valproate while pregnant, and that you are informed and understand the recommendation to prevent pregnancy when using valproate.

I am taking valproate and am pregnant

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

First of all, you must talk to your doctor as soon as possible. This is so you can discuss your options. Your doctor may advise you to switch to another type of treatment and explain how to make the change from valproate to this new treatment.

Children whose mothers used valproate during pregnancy are exposed to a higher risk of:

- birth defects,
- developmental problems and learning disabilities.

These can have a negative impact on your child's life.

In certain circumstances, it may not be possible to switch to another treatment. Ask your doctor for more information.

At your appointment with your doctor, you will be asked to read a risk acknowledge form that explains the risk of birth defects. This is to make sure that you are informed and understand the risk of using valproate while pregnant, and that you are informed and understand the recommendation to prevent pregnancy when using valproate.

You will be closely monitored during pregnancy to ensure that your condition is under control and to check your child's development.