



CAN'T **YOU** see  
THAT you ARE  
**NOT** WIRED LIKE  
**ME**  
YOU WILL never  
KNOW THE WAY  
I feel and look  
and **SEE**

*Christy Smith  
age 11*

Valproate

GUIDE

FOR PATIENTS

# PATIENT GUIDE

## Valproate, Contraception and Pregnancy: what you should know

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

It is a risk minimisation measure part of the valproate Pregnancy Prevention Programme aiming to minimise pregnancy exposure during treatment with valproate. It contains key information about the risk of valproate use during pregnancy.

It is important to read this if your doctor has recommended valproate as the best treatment for you.

Please note:

- The risks of using valproate during pregnancy are the same for all females.
- 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 as it contains the most up to date information on your medicine.
- You might find it helpful to talk to your partner, friends and/or family about this booklet,
- Ask your doctor or pharmacist if you have any questions.

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

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

## KEY INFORMATION TO REMEMBER

1. Valproate is an effective medicine for epilepsy and bipolar disorder.
2. Valproate should only be taken by women of childbearing potential, or female adolescents unless nothing else works. This is because valproate can seriously harm an unborn child when taken during pregnancy.
3. Should you experience an illness, never stop taking valproate unless your doctor tells you to do so.
4. Always use effective contraception when taking valproate and use contraception for the whole time you are taking valproate. Do not stop or interrupt using contraception at any time.
5. Your doctor will recommend effective contraception for you. This is to stop you having an unplanned pregnancy.
6. Schedule an urgent appointment with your doctor if you think you are pregnant.
7. Consult your doctor promptly if you are thinking about having a baby and do not stop using contraception or your valproate medicine until you have had the discussion with them.
8. Never stop taking valproate unless your doctor tells you because your illness may become worse.
9. Remember to visit your doctor/healthcare practitioner experienced in the management of epilepsy or bipolar disorder regularly- at least annually.
10. 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.

## WHAT ARE THE RISKS OF TAKING VALPROATE DURING PREGNANCY?

### Risks to your unborn child:

1. If you take valproate when you are pregnant it can seriously harm your unborn child.
2. The risks are higher with valproate than with other medicines for epilepsy or bipolar disorder.
3. 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 or bipolar disorder.

### How could my child be harmed?

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

1. Birth defects noted upon delivery.
2. Impaired physical and mental development as the baby grows.

## 1. BIRTH DEFECTS

Taking valproate during pregnancy can cause serious birth defects.

Face and skull malformations - including facial dysmorphism, 'cleft lip' and 'cleft palate'. This is where the upper lip or bones in the face are split, craniostenosis (a birth defect where the sutures (flexible joints) between a baby's skull bones close too early, before the brain is fully formed, causing the skull to grow abnormally and potentially restricting brain development).

Malformations of the limbs, heart, kidney, and sexual organ malformations, and multiple anomalies involving various body systems.

## 2. IMPAIRED PHYSICAL AND MENTAL DEVELOPMENT

Taking valproate while pregnant can have adverse effects on mental and physical development of the exposed children

In women who take valproate while pregnant:

Up to 30 to 40 children in every 100 may experience delays in their early development.

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 (speaking and understanding).
- Memory problems.

There is limited data on the long-term outcomes.

Available data show that children exposed to valproate in utero are at increased/ risk of autistic spectrum disorder (approximately three-fold) and childhood autism (approximately five-fold) compared with the general study population.

Limited data suggests that children exposed to valproate in utero may be more likely to develop symptoms of attention deficit/hyperactivity disorder (ADHD).

## WHAT SITUATION APPLIES TO 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.

## I. I AM STARTING TREATMENT WITH VALPROATE

Your doctor will explain to you why he/she feels valproate is the right medicine for you and tell you about all the known risks.

### a. If you are not of childbearing age:

- 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 medical practitioner experienced in the management of epilepsy or bipolar disorder once you experience your first menstrual period during valproate use.

### b. If you are already of childbearing age:

- ° 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 the whole time when you are taking valproate:
  - Do not stop or interrupt using 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 of and have understood all the risks related to the use of valproate during pregnancy and recommendations to avoid you becoming pregnant while taking valproate.
- ° If you decide on Family Planning, 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.

## II. 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 duration of valproate treatment; Do not stop or interrupt using contraception at any time.
- ° Consult your doctor immediately when you suspect pregnancy.
- ° 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 of and have understood all the risks related to the use of valproate during pregnancy and recommendations to avoid you becoming pregnant while taking valproate.

## III. 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 to 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.
- ° Switching medication takes time.
- ° Your doctor will advise you as to when you can plan for conception after complete cessation of valproate.
- ° You need to talk about what can be done to reduce the risks for your baby's health while keeping your illness under control.
- ° 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.

## IV. 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 or bipolar disorder may become worse.

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

- Birth defects and
- Impaired physical and mental development.

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 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 illness is controlled.
- It is also to check how your baby is developing.

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