

**THIS GUIDE IS FOR
GIRLS (OF ANY AGE)
AND WOMEN WHO CAN
BECOME PREGNANT
TREATED WITH
VALPROATE**

VALPROATE PATIENT GUIDE ON CONTRACEPTION AND PREGNANCY

*Read this guide
along with the patient
information leaflet for
a complete product information*

VALPROATE* EPILIM

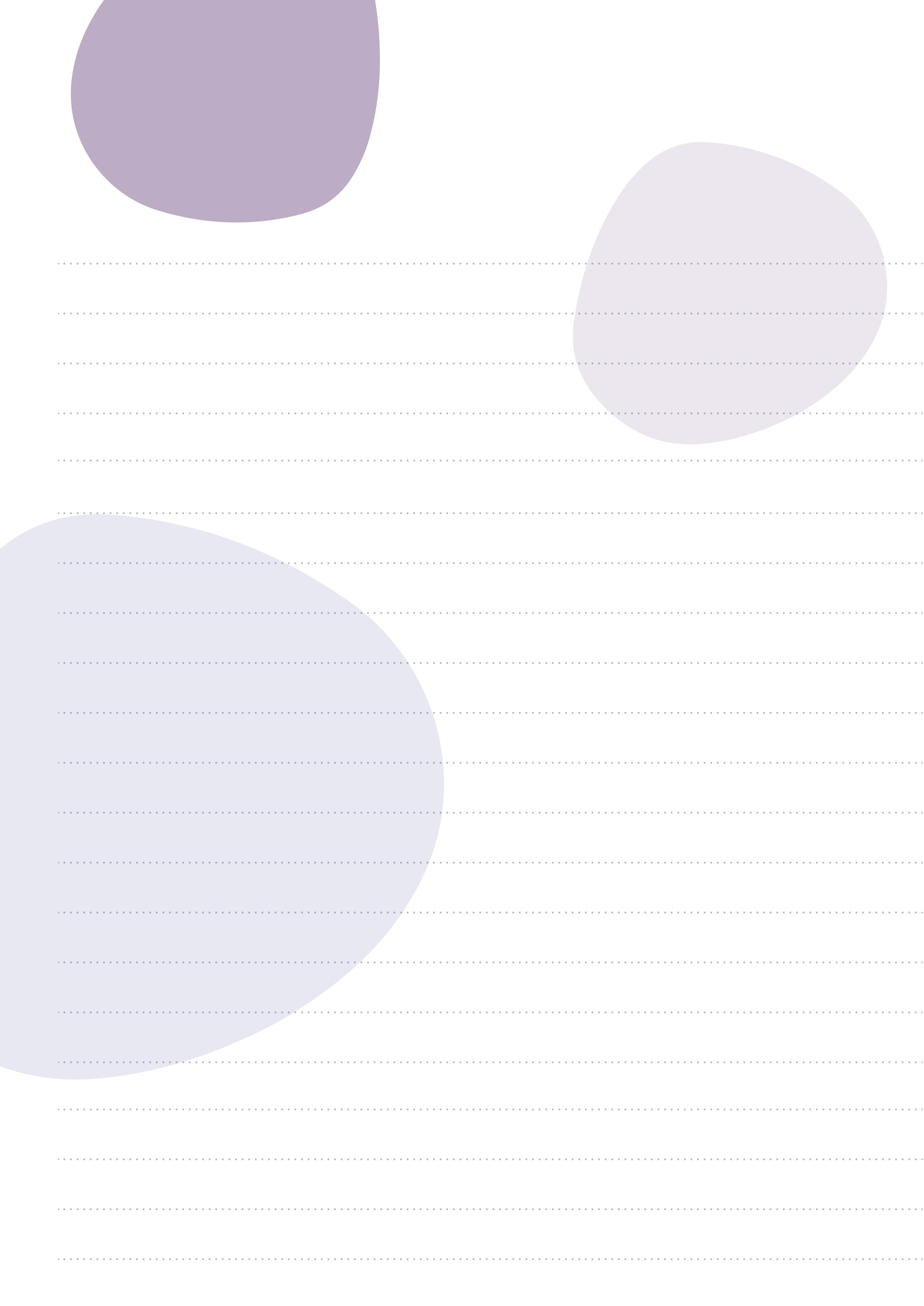
CONTRACEPTION AND PREGNANCY: WHAT YOU SHOULD KNOW

This guide contains key information about the risk of valproate*
use during pregnancy.

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

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

*Valproate also known as Epilim



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PLEASE REFER TO THE PATIENT INFORMATION LEAFLET FOR MORE DETAILED INFORMATION



Key information to remember



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

If you are taking valproate* and are able to become pregnant:

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

If you are thinking about having a baby:

- Speak first to your doctor before stopping your contraception.
- Never stop taking valproate* unless your doctor tells you because your condition may become worse.

If you are taking valproate* and have become pregnant:

- Do not stop taking valproate*- this is because your epilepsy or bipolar disorder may become worse.
- Talk promptly 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.



At treatment initiation and during the annual visit, both yourself and your specialist will read **and sign** an Annual Risk Acknowledgement Form to ensure you know and understand the risks related to the use of valproate* during pregnancy and the need to avoid becoming pregnant while taking valproate*

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What are the risks to your baby from taking valproate* during pregnancy?



Taking valproate* during pregnancy can cause serious birth defects

- In women treated with valproate* around 11 babies in every 100 may have a birth defect, while in the general population it is around 2-3 babies in every 100.

What type of birth defects can happen?

- Reported birth defects with valproate* include for example:
 - Malformation of spine bones (spina bifida).
 - Face and skull malformations – including for example harelip.
 - Malformations of the limbs, heart, kidney, urinary tract, sexual organs and of the eyes that may affect vision.
 - Hearing problems or deafness.

Taking valproate* 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 for example:
 - 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 are more likely to have autism or autistic spectrum problems and are at increasing risk of developing Attention Deficit and/or Hyperactivity Disorder.

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

- In women who take valproate*, 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.

For the risks of birth defects and neurodevelopment problems, the higher the dose the higher the risks but all doses carry a risk.

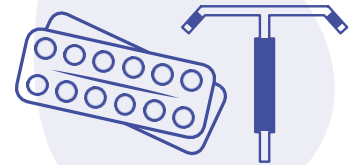
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Contraception (birth control)

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



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



Please refer to your doctor, or gynaecologist/obstetrician or midwife or nurse or pharmacist for complete counselling on the best contraceptive methods 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.

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



"I AM STARTING TREATMENT WITH VALPROATE*"

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

- You should only be treated with valproate* if you are not pregnant and you are using effective contraception (birth control).
- Your doctor will ask you to perform a pregnancy test and will counsel you on the methods of contraception.
- You will need to review your treatment with your specialist regularly – at least once a year.

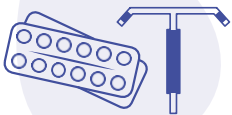


At treatment initiation and during the annual visit, both yourself and your specialist will read **and sign** an Annual Risk Acknowledgement Form to ensure you know and understand the risks related to the use of valproate* during pregnancy and the need to avoid becoming pregnant while taking valproate*.

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"I AM TAKING VALPROATE* AND NOT PLANNING TO HAVE A BABY"



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

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



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

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



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

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"I AM TAKING VALPROATE* AND PLANNING TO HAVE A BABY"



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

- o Your specialist may need to change your valproate* treatment a long time before you become pregnant - this is to make sure your condition is stable.
- o It is important that you do not become pregnant until you have discussed your options with your specialist.
- o Review your treatment with your specialist regularly – at least once a year.



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

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"I AM TAKING VALPROATE* AND I THINK I MAY BE OR I AM PREGNANT"

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

Talk urgently to your specialist 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* 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 both yourself and your specialist will read **(and sign)** an Annual Risk Acknowledgement Form to ensure you know and understand the risks related to the use of valproate* during pregnancy

*Valproate also known as Information.



PLEASE REFER TO THE PATIENT INFORMATION LEAFLET FOR MORE DETAILED INFORMATION

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I am a girl (of any age), what does this mean for me?



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



Babies from mothers treated by valproate* can have very severe health problems.

One day, you might have a baby.
That is why you need to strictly follow these recommendations

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 doctor to discuss your treatment.

I already have had my first
periods



Your doctor will check that you are not pregnant.



Your doctor will give you a birth control medicine called a contraceptive, even if you do not have sexual relationships. You should **always use birth control** while you are taking valproate*.

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*** without asking your doctor.



In any case, you will need to see your doctor at least once a year.

During this visit your doctor will:

- o check that valproate* is still the right medicine for you,
- o talk to you about valproate*, and
- o ask you (or your parents/legal guardians) to sign a paper to ensure you 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* without talking to your doctor.

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Reporting of Adverse Drug Reactions (ADRs):

You may report any adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring at the official website [npra.moh.gov.my](https://www.npra.gov.my):
<https://www.npra.gov.my/index.php/en/consumers/reporting/reporting-side-effects-to-medicines-conserf-or-vaccines-aefi-2.html>

The Sanofi logo consists of the word "sanofi" in a bold, lowercase, sans-serif font. The letter 's' is black, while the letters 'a', 'n', 'o', 'f', and 'i' are purple. There are small purple dots above the 'a' and 'i'.

Sanofi-Aventis (Malaysia) Sdn Bhd (334110-P)
Unit TB-18-1, Level 18, Tower B, Plaza 33,
No 1 Jalan Kemajuan, Seksyen 13,
46200 Petaling Jaya, Selangor Darul Ehsan,
Malaysia
Tel: +60376510800

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