

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

VALPROATE* PATIENT GUIDE ON CONTRACEPTION AND PREGNANCY

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

VALPROATE* (DEPALEPT CHRONO)

CONTRACEPTION AND PREGNANCY: WHAT YOU SHOULD KNOW

This guide contains key information about the risks of Valproate* use during pregnancy.

It is important that you read this guide if your doctor recommended Valproate* as the best treatment for you.

The risks associated with Valproate* usage during pregnancy apply to all girls (of any age) and women

Ask your doctor or pharmacist if you have any questions.

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

* The trade name of Valproate is Depalept Chrono.

PLEASE REFER TO THE PATIENT LEAFLET FOR MORE DETAILED INFORMATION.

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NOTES

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1

Key information to remember



- Valproate* is an effective medicine for epilepsy and bipolar disorder.
- Valproate* should be taken by women and girls (of any age) only if other treatments are ineffective or not tolerated. 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:

- Do not stop using contraception until you consult your doctor.
- 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 (neurologist or psychiatrist) regularly - at least once a year.

At treatment initiation and during the annual visit, both yourself and your specialist will discuss the risks related to the use of Valproate* during pregnancy.

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2

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



The higher the dose the higher the risk, but all doses carry a risk, including when Valproate* is used in combination with other medicines to treat epilepsy or bipolar disorder.

Taking Valproate* during pregnancy can cause serious birth defects.

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

What type of birth defects can happen?

- Reported birth defects with Valproate* include for example:
 - Spina bifida
 - Face and skull malformations - including 'cleft lip'
 - 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.

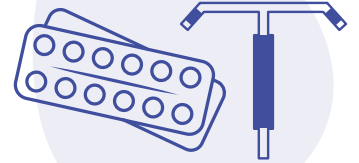
- In women treated with Valproate* during pregnancy: Up to 30 to 40 pre-school children in every 100 may have problems with neurodevelopment disorders for example:
 - Being late in learning to walk and talk.
 - Lower intelligence than other children of the same age.
 - Poor speech and language skills.
 - Memory problems.
- Children of mothers who take Valproate* in pregnancy are at higher risk for autism or autistic spectrum problems, and are at increasing risk of developing Attention Deficit and/or Hyperactivity Disorder (ADHD).

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3

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 gynecologist/obstetric specialist for complete counselling on the best contraceptive method 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 doctor or gynecologist will discuss this with you.

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4

What does this information mean for me?



"I am starting treatment with Valproate*."

Your doctor will explain to you why they think Valproate* is the right medication for you and all the known risks. Your doctor should only treat you with Valproate* when none of the other treatments are effective or tolerated.

- 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. Tell your doctor immediately if you are pregnant or think you might be pregnant.
- Review your treatment with your specialist (neurologist or psychiatrist) regularly - at least once a year.

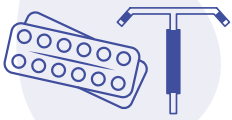


At treatment initiation and during the annual visit, both yourself and your specialist will discuss the risks related to the use of Valproate* during pregnancy.

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"I am taking Valproate* and I am not planning to have a baby"



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

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



Consult with your doctor or gynecologist/obstetric specialist on the method of contraception.

Tell your doctor immediately if you are pregnant or you think you might be pregnant. Do not stop taking Valproate* until you have discussed this with your doctor, as this could be dangerous for you and your baby.



Review your treatment with your specialist (neurologist or psychiatrist) regularly – at least once a year. During the annual visit, both yourself and your specialist will discuss the risks associated with Valproate* treatment during pregnancy.

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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 doctor 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 doctor.
- o Ask your doctor about taking folic acid when planning a pregnancy. Folic acid can reduce the overall risk in all pregnancies of spina bifida (a deformity of the spine – open back) and reduce early miscarriage. However, it is unlikely that folic acid intake would reduce the risk of birth defects associated with the intake of Valproate*.
- o Review your treatment with your specialist (neurologist or psychiatrist) regularly - at least once a year.



During the annual visit, both yourself and your specialist will discuss the risks related to the use of Valproate* during pregnancy.

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"I am taking Valproate* and I am pregnant or I think I may be pregnant"

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

Talk urgently 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.



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

- Birth defects
- Neurodevelopment and learning problems.

These can both seriously affect your child's life.

Make sure that you and your baby 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 the annual visit, both yourself and your specialist (neurologist or psychiatrist) will discuss the risks related to the use of Valproate* during pregnancy.



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5

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 women 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*




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 suspected adverse reactions to the Ministry of Health by
using an online form <https://sideeffects.health.gov.il>
Or report directly to Sanofi : 09-8633081

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