

PATIENT GUIDE

What women and girls need to know about

Epival® (Sodium Valproate)

This booklet is for you (or your parent/caregiver/responsible person) if you are a girl (of any age) or a woman of childbearing potential taking any medicine containing valproate.

It is part of “**prevent**” – the valproate pregnancy prevention programme, which aims to minimize the risks that could occur through the use of valproate during pregnancy.

Valproate can seriously harm an unborn baby. Always use effective contraception during your treatment. If you are thinking about becoming pregnant, or you become pregnant, talk to your GP or specialist straight away.

Do not stop taking valproate unless your doctor tells you to.

Please keep this booklet. You may need to read it again.

This booklet is for girls (of any age) and women who are able to get pregnant and are taking any medicine that contains valproate

- 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, whatever you are taking it for.

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.

You might find it helpful to talk about this booklet with your partner, friends and family.

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

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■ Contraception for girls and women who are able to become pregnant

■ Why do I need to use contraception?

This is to stop you getting pregnant on valproate.

When taking valproate always use effective contraception that has been recommended by your doctor, at all times during your treatment with valproate.

Contraception must be used even if you are not currently sexually active, unless in your doctor's opinion there are compelling reasons for assuming there is no risk of pregnancy.

■ What type of contraception should I use?

Discuss with your GP, specialist, or gynaecologist/obstetrician for advice on the best method of contraception for you.

■ What are the risks of taking valproate during pregnancy?

Risks to your unborn baby.

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

- The risks are higher with valproate than with other medicines for epilepsy
- The risks are present even with smaller doses of valproate.

How could my baby be harmed?

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

- Birth defects when the baby is born
- Problems with development and learning as the child grows up.

Birth defects

Taking valproate during pregnancy can cause serious birth defects.

- For women who take valproate while pregnant, around 10 babies in every 100 will have a birth defect.
- For women in general, around 2 to 3 babies in every 100 will have a birth defect.

What type of birth defects can happen?

- 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 bones in the face are split.
- Malformations of the limbs, heart, kidney, urinary tract and sexual organs.
- Taking folic acid is generally recommended for anyone trying to have a baby as it can reduce the risk of spina bifida in all pregnancies. However, it is unlikely to reduce the risk of birth defects from valproate.

Development and learning problems

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

In women who take valproate while pregnant:

- 30–40 children in every 100 will have problems with development.

The following effects on development are known:

- 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 autism spectrum disorders. The children may be more likely to have signs of Attention Deficit Hyperactivity Disorder (ADHD).

■ I am starting treatment with valproate

■ What does this mean for me?

Your specialist will explain to you why they feel valproate is the right medicine for you and tell you about 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/responsible person 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 parent/caregiver/responsible person should contact your GP or specialist as soon as you start your periods during valproate use to have your treatment reviewed.

■ If you are already old enough to become pregnant:

- Your doctor should only treat you with valproate if nothing else works.
- Your doctor should only treat you with valproate if you are not pregnant and you are using contraception.
- Your specialist will ask you to take a pregnancy test before starting valproate, and may ask you to repeat this at intervals whilst treatment continues. This is to make sure you are not pregnant.
- It is important that you always use effective contraception at all times during treatment with valproate. This is to make sure you do not become pregnant.
- You will need to review your treatment with your specialist regularly (at least once a year).
- At the initial visit and at each yearly review, your specialist will ask you to read and sign an Annual Risk Acknowledgement Form to make sure you know and have understood all the risks related to the use of valproate during pregnancy and the need to avoid becoming pregnant while taking valproate.

■ If you decide you want to plan to become pregnant, talk to your doctor about this as soon as possible

- Do not stop taking valproate or using contraception until you have been able to discuss this with your doctor.
- You and your specialist should agree on what to do with your treatment before you start trying for a baby.
- You need to talk to your doctor about the risks for your baby's health while keeping your illness under control

■ I am taking valproate and not planning to become pregnant

■ What does this mean for me?

If you are taking valproate and do not plan to have a baby, you must use an effective contraception method at all times during your treatment.

Talk to your GP, specialist or gynaecologist/obstetrician.

Talk urgently to your GP or specialist if you think you are pregnant.

Do not stop taking valproate until you have discussed this with your doctor even if you have become pregnant.

You will need to review your treatment with your specialist regularly (at least once a year).

During the annual visit your specialist will ask you to read and sign an Annual Risk Acknowledgement Form to make sure you know and have understood all the risks related to the use of valproate during pregnancy and the need to avoid becoming pregnant while taking valproate.

■ I am taking valproate and planning to become pregnant

- What does this mean for me?

If you are planning a baby, first talk to your GP or specialist 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 have discussed your options with your specialist.
- Your specialist may need to change your medicine a long time before you become pregnant – this is to make sure your condition is stable.
- Valproate can harm babies even in early pregnancy. It is therefore important that you do not delay seeing your GP or specialist if you think you may be pregnant.

■ I am taking valproate and I think I may be, or I am pregnant

- What does this mean for me?

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

Talk urgently to your GP or specialist. This is so that you can talk about your options. Your specialist may tell you that you need to switch to another treatment and will explain how to make the change from valproate to this new treatment.

If you take valproate during pregnancy, your child will have a higher risk of:

- birth defects and
- developing and learning problems.

These can both seriously affect your child's life.

In some circumstances, it may not be possible to switch to another treatment.

Please refer to your specialist for additional information.

During this visit your specialist will ask you to read and sign an Annual Risk Acknowledgement Form to make sure you know 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 condition is controlled.
- It is also to check how your baby is developing.

■ Key information to remember

- Valproate is an effective medicine for epilepsy.
- Valproate can **seriously harm an unborn child** when taken during pregnancy – it should not be taken by women and girls unless nothing else works. Whatever your condition **never stop taking valproate before discussing** with your doctor first.
- When taking valproate **always use effective contraception** that has been recommended by your doctor at all times during your treatment – so that you do not have an unplanned pregnancy.
- Make an **urgent** appointment with your GP or specialist if you think you are pregnant.
- Consult your doctor if you are thinking about having a baby and do not stop using contraception until you and your specialist agree on what to do with your treatment.
- Remember to visit your specialist regularly – at least once a year.
- During this visit both yourself and your specialist will discuss and sign an Annual Risk Acknowledgement Form to ensure you are well aware of and understand the risks of valproate use during pregnancy.

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

Call for reporting

Report suspected adverse drug reactions associated with Epival® (Sodium Valproate) by contacting:

Local representative / Cigalah Group

Sharafiyah District - Al Yousfia Building

P.O. Box 19435 - Ali Bin Abi Taleb Street, Jeddah, 21435 Saudi Arabia

Tel: +966-12-6148259 - Mob: +966-539455825 - Fax: +966-12-6148458

Email: drug-safety@cigalah.com.sa - moghamdi@cigalah.com.sa

The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA)

SFDA call center: 19999

Toll free phone: 8002490000 - Fax: +966-11-2057662

E-mail: npc.drug@sfda.gov.sa - Website: <http://ade.sfda.gov.sa/>

References

1. Epival® Leaflet