THIS GUIDE IS FOR FEMALE PATIENTS TREATED WITH VALPROATE WHO CAN BECOME PREGNANT



PATIENT GUIDE: What you need to know about valproate

prevent
valproate pregnancy prevention programme

Read this guide along with the patient information leaflet which is included in each box of your medicine

This medicine will be referred to as valproate throughout this guide and covers the brands Epilim, Depakote, Alprolep, Belvo, Convulex, Dyzantil, Episenta, Epival, Syonell & Sodium Valproate (Crescent, Desitin, Strandhaven/Somex, Wockhardt).

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

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

Information about the use of valproate in female patients who can become pregnant and risks of valproate use during pregnancy can also be found online at www.medicines.org.uk by entering "valproate" in the search box and then clicking on "Risk Materials" next to any of the medicines listed. You can also search online for "MHRA valproate".

Risk minimisation material fulfils the conditions of the marketing authorisation and has been approved by MHRA.

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Do not stop taking valproate unless your specialist tells you to. This is because your condition may become worse, including an increased risk of seizure if you are being treated for epilepsy and an increased risk of relapse if you are being treated for bipolar disorder.

This guide is for you (or your parent/caregiver/responsible person) if you are taking any medicine containing the active ingredient valproate. Valproate is available as various brand names which are listed at the top of this guide. You might find it helpful to talk about this guide with your partner, friends and family.

It contains key information about the risks of valproate.

Ask your specialist, GP or other health professional who may be involved in the management of your condition (gynaecologist/obstetrician, midwife, nurse, pharmacist etc.) if you have any questions.

CONTENTS

1 **Key information to remember** 3

2 **What are the risks of taking valproate during pregnancy?** 4
- Birth defects
- Types of birth defects

3 **Birth control (Contraception)** 5

4 **What does it mean for me?** 6-9
- "I am aged under 55 years and starting treatment with valproate" 6
- "I am not planning to have a baby" 7
- "I am planning to have a baby" 8
- "I have an unplanned pregnancy" 9

5 **I am a female child,what does this mean for me?** 10

Other sources of Information 11

1 Key information to remember

- Valproate is used to treat epilepsy and bipolar disorder.
- Valproate should only be taken by female patients aged under 55 years when two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks.

Whatever your condition, never stop taking valproate before discussing with your specialist first. This is because your condition may become worse, including an increased risk of seizure in those being treated for epilepsy and an increased risk of relapse in those treated for bipolar disorder.

During your first visit, your specialist will discuss the annual risk acknowledgement form and will ask you to sign it and keep a copy.

A second specialist will also consider your treatment and sign the form. There are various ways your treatment can be reviewed by a second specialist. You will not need an appointment to see another specialist unless you wish to do so.

I am aged under 55 years and starting treatment with valproate

Your specialist will discuss the benefits and risks of valproate with you or your caregiver:

- You should only be treated with valproate if your specialist has discussed with you and another specialist and have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks.

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

- Use an effective method of birth control (contraception) recommended by your General Practitioner (GP), specialist, sexual health and contraception clinic, or contraception service in your community pharmacy, at all times during your treatment with valproate – this is to reduce the risk of an unplanned pregnancy.

If you are thinking about having a baby:

- First consult your GP, to be urgently referred to your specialist. Do not stop using your method of birth control (contraception) until you and your specialist agree on what treatment option would be in your best interests.

If you are taking valproate and have become pregnant:

- Make an urgent appointment with your GP. Your GP will refer you immediately to your specialist who will then advise you further.

If you are caregiver of a female patient who has not experienced their first period (menarche):

- Contact your child's GP as soon as your child experiences their first period, to be referred to their specialist.

You should see your specialist regularly, at least once a year, and your specialist should discuss and complete the Annual Risk Acknowledgement Form with you. Your specialist will consult with you and decide with another specialist whether valproate is appropriate and may switch you to another medicine.

2 What are the risks of taking valproate during pregnancy?

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.

Taking valproate during pregnancy can cause serious birth defects.

- In female patients treated with valproate around 11 babies in every 100 will 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?

- Birth defects may result in disabilities which may be severe and/or permanent. These may include:
  - 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, sexual organs
  - Eye malformations in association with other birth defects that may affect vision.
  - Hearing problems or deafness.

Taking valproate whilst pregnant could affect your child's development and how they grow after birth, which may lead to permanent disability.

- In female patients who take valproate whilst pregnant, up to 30-40 children in every 100 may have problems with development 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 during pregnancy are at an increased risk of having autism and related disorders and are at increasing risk of developing Attention Deficit and/or Hyperactivity Disorder (ADHD).
- Children of mothers who take valproate during pregnancy, may have a lower weight than expected for their age at birth.

Taking folic acid is generally recommended for anyone trying to have a baby as it can reduce the risk of spina bifida in pregnancies. However, it is unlikely to reduce the risk of spina bifida related to valproate.

3 Birth control (contraception)

This is to stop you getting pregnant whilst taking valproate.

If you are able to get pregnant, use an effective method of birth control (contraception) recommended by your GP, specialist, sexual health and contraception clinic, or contraception service in your community pharmacy, at all times during your treatment with valproate.

Discuss with your GP, specialist, sexual health and contraception clinic, or contraception service in your community pharmacy for advice on the method of birth control (contraception) that is the most appropriate for you.

The most effective methods of birth control (contraception) include contraceptive implants and intrauterine devices with copper or hormones.

Some birth control pills (oestrogen-containing birth control pills) may lower valproate levels in your blood. Make sure you mention valproate when talking about the method of birth control (contraception) that is the most appropriate for you.

An effective method of birth control (contraception) must be used even if you are not currently sexually active unless, in your specialist's opinion, there are compelling reasons for determining there is no risk of pregnancy.

4 What does this mean for me?

"I AM AGED UNDER 55 YEARS STARTING TREATMENT WITH VALPROATE"

You/your child should only be treated with valproate if your specialist has discussed with you and another specialist and have agreed that your/your child's condition does not respond to other treatments and the benefits of treatment outweigh the risks.

FEMALE PATIENTS WHO HAVE STARTED HAVING PERIODS:

- You should only be treated with valproate if your specialist has consulted with you about the risks and benefits and decided with another specialist that your condition does not respond to other treatments and the benefits outweigh the risks.
- If you are able to get pregnant, your GP or specialist will discuss the need for birth control (contraception) with you/your child.
- Your specialist may ask you to perform a pregnancy test.
- Your specialist will review your/your child's treatment regularly, and at least once a year.

At the initial visit and at each annual review, your specialist will remind you/your child about the risks and discuss and complete an Annual Risk Acknowledgement Form to make sure you know and have acknowledged all the risks related to the use of valproate during pregnancy and the need to avoid becoming pregnant whilst taking valproate.

If there is a permanent reason that these risks do not apply to you (e.g., if you are post-menopausal or have had a hysterectomy), you will not be asked to sign the form.

During these visits your specialist will decide with you/your child whether you/your child should continue receiving treatment with valproate or whether another medicine should be prescribed. Your specialist may discuss and confirm this decision with another specialist.

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

You must use an effective method of birth control (contraception) at all times during your treatment.

Talk to your GP, specialist or gynaecologist/obstetrician, midwife/professional at the sexual health and contraception clinic, or contraception service in your community pharmacy if you need advice on birth control (contraception).

Tell your GP immediately to be urgently referred to your specialist, if you think you are pregnant.

Do not stop taking valproate until you have discussed this with your specialist. This is because your condition may become worse, including an increased risk of seizure in those being treated for epilepsy and an increased risk of relapse in those treated for bipolar disorder.

Your specialist should review your treatment with you regularly (at least once a year).

During the annual visit your specialist will discuss and complete an Annual Risk Acknowledgement Form with you to make sure you know and have acknowledged all the risks related to the use of valproate during pregnancy and the need to avoid becoming pregnant whilst taking valproate.

If there is a permanent reason that these risks do not apply to you (e.g., if you are post-menopausal or have had a hysterectomy) the form will not be completed in full, but you may be asked to sign the form to acknowledge that the risks do not apply to you.

During these visits your specialist will decide with you whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. Your specialist may discuss and confirm this decision with another specialist.

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

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

o Your specialist may need to change your medicine to another treatment a long time before you become pregnant - this is to make sure your condition is stable before you become pregnant.

o Valproate can harm babies even in early pregnancy.

First schedule an appointment with your GP to be referred to your specialist but:

o Do not stop taking valproate – this is because your condition may become worse, including an increased risk of seizure in those being treated for epilepsy and an increased risk of relapse in those treated for bipolar disorder.

o Do not stop using your method of birth control (contraception) until you have discussed this with your specialist.

During this visit your specialist will reassess whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. They will make sure you are well aware of and have understood all the risks and advice related to the use of valproate during pregnancy.

"I AM TAKING VALPROATE AND I HAVE AN UNPLANNED PREGNANCY "

Do not stop taking valproate unless your specialist tells you to - this is because your condition may become worse, including an increased risk of seizure in those being treated for epilepsy and an increased risk of relapse in those treated for bipolar disorder.

Immediately schedule an appointment with your GP to be urgently referred to your specialist. Your specialist will assess your condition and discuss your treatment options. Your specialist may advise you that you need to switch to another treatment and will explain how to make the change from valproate to a new treatment.

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

o Birth defects

o Physical and mental development problems.

o Lower weight than expected for their age at birth

These can seriously affect your child's life and may lead to permanent disability.

In some circumstances, it may not be possible to switch to another treatment. Please refer to your specialist for additional information.

You will be monitored very closely:

o This is to make sure your condition is controlled.

o It is also to check how your baby is developing.

5 I am a female child what does this mean for me?

You have been given valproate 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

You should know about the risks of valproate when used during pregnancy.

I have had my first period

You/your guardian should contact your GP who will refer you to your specialist.

Your specialist will decide with you/your caregiver and another specialist whether your condition does not respond to other treatments and the benefits outweigh the risks and if not, they will try to switch you to another medicine.

Your specialist may ask you to perform a pregnancy test, because you must not take valproate If you are pregnant.

I have started having periods

You should be treated with valproate only if your specialist has consulted with you about the risks and benefits and decided with another specialist that your condition does not respond to other treatments and the benefits outweigh the risks.

If you are able to get pregnant your GP or specialist will discuss the need for birth control (contraception) with you/ your guardian.

Your specialist may ask you to perform a pregnancy test.

Your specialist will review your treatment regularly, and at least once a year.

At the initial visit and at each annual review, your specialist will remind you about the risks and discuss and complete an Annual Risk Acknowledgement Form to make sure you know and have acknowledged all the risks related to the use of valproate during pregnancy and the need to avoid becoming pregnant whilst taking valproate.

If there is a permanent reason that these risks do not apply to you (e.g., if you are post-menopausal or have had a hysterectomy), you will not be asked to sign the form.

During these visits your specialist will decide with you whether you should continue receiving treatment with valproate or whether another medicine should be prescribed. Your specialist may discuss and confirm this decision with another specialist.

Never stop taking valproate without talking to your specialist.

TO BE READ ALONGSIDE THE PIL IN THE BOX OF YOUR MEDICINE.

Other sources of information

You may find the following organisations helpful if you are looking for information about epilepsy or bipolar disorder and how to effectively manage your condition:

Epilepsy Action
www.epilepsy.org.uk
0808 800 5050

Bipolar UK
www.bipolaruk.org

Epilepsy Society
www.epilepsysociety.org.uk
0300 102 0024

Mind
www.mind.org.uk
0300 123 3393

Young Epilepsy
www.youngepilepsy.org.uk

SUDEP Action:
www.sudep.org
01235 772 852

A leaflet specifically for girls and young women can be found www.medicinesforchildren.org.uk/medicines/sodium-valproate-for-preventing-seizures/

You may find the following organisations helpful if you are looking for information about Fetal Valproate Spectrum Disorder/Fetal Anti-Convulsant Syndrome:

Organisation for Anti-Convulsant Syndrome (OACS):
www.oacscharity.org
07904 200364

Independent Fetal Anticonvulsant Trust (INFACT)
www.infactuk.com

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

For further copies of this guide, please contact Sanofi Medical Information department on:

0800 035 2525 or email **UK-Medicalinformation@sanofi.com**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. You can talk to your doctor, pharmacist or nurse or you can also report side effects directly via the Yellow Card Scheme at **www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store.