

Patient Guide: What you need to know about valproate

This medicine will be referred to as valproate throughout this guide and cover the brand Votellaz

This guide is for you (or your parent/caregiver/responsible person) if you are taking any medicine containing the active ingredient valproate (as sodium valproate or valproic acid).

this guide with your partner, friends and family. It contains key information about the risks of valproate.

READ THIS GUIDE ALONG WITH THE PATIENT INFORMATION LEAFLET WHICH IS INCLUDED IN EACH BOX OF YOUR MEDICINE.

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

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.

New patients:

- For patients aged under 55 years, two specialists must agree that your condition does not respond to other treatments or other treatments are not tolerated.

Female patients:

- For female patients aged under 55 years taking valproate, two independent specialists must agree that your condition does not respond to other treatments or other treatments are not tolerated and document this at your next annual review.
- New information: the risk of eye malformations for exposed pregnancies.

Male patients:

- New information: the risks associated with use of valproate in male patients.

Contents

1. Key information to remember	3-4
2. Information for female patients	5-9
i. An effective method of birth control (contraception)	5
ii. What are the risks of taking valproate during pregnancy?	5
- Taking valproate during pregnancy can cause serious birth defects.	
- What type of birth defects can happen?	
- Taking valproate whilst pregnant could affect your child's development and how they grow after birth, which may lead to permanent disability.	
iii. What does this mean for me?	6
- Female patients aged under 55 years starting treatment with valproate	
a. Female children who have not yet experienced their first period	
b. As soon as your child experiences their first period whilst taking valproate	
c. Female patients who have started having periods	
- I am taking valproate and not planning to have a baby	
- I am taking valproate and planning to have a baby	
- I am taking valproate and I have an unplanned pregnancy	
3. Information for male patients	10
i. What are the risks of taking valproate?	10
ii. What does this mean for me?	10
4. Notes	11

1. Key information to remember

- Valproate is used to treat epilepsy
- For male patients aged under 55 years who have not used valproate before and in female patients aged under 55 years: this medicine is only used when two specialists have agreed that your condition does not respond to other treatments.
- 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 risk acknowledgement form and will ask you to sign it and keep a copy of it.
- 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.

• For female patients

- o Valproate can seriously harm an unborn baby when taken during pregnancy - it should not be taken by female patients aged under 55 years unless two specialists have agreed that your condition does not respond to other treatments and the benefits of treatment outweigh the risks.
- o If you are able to get pregnant, use an effective method of birth control (contraception) that has been recommended by your General Practitioner (GP), specialist, OBGYN, at all times during your treatment with valproate - this is to reduce the risk of an unplanned pregnancy.
- o If you think you are pregnant, make an urgent appointment with your GP. Your GP will refer you immediately to your specialist who will then advise you further.
- o Consult your GP, to be urgently referred to your specialist, if you are thinking about having a baby. 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.

- o If you are caregiver of a female patient who has not yet 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.
- o 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.

• For male patients

- o Valproate should not be started by male patients aged under 55 years unless two specialists have agreed that your condition does not respond to other treatments and the benefits of valproate outweigh the risks.
- o Valproate may cause infertility in men, that may be reversible after treatment is stopped or the dose is reduced in some patients.

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

2. Information for female patients

i. An effective method of birth control (contraception)

Why do I need to use an effective method of 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) that has been recommended by your GP, specialist, OBGYN, at all times during your treatment with valproate.
- 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.

What type of effective birth control (contraception) should I use?

- Discuss with your GP, specialist, gynaecologist/obstetrician/midwife, 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.

ii. 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.

- For women who take valproate while pregnant, around 11 babies in every 100 will have a birth defect.
- For women in the general population, around 2 to 3 babies in every 100 will have a birth defect.

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 and sexual organs.
- Eye malformations in association with other birth defects - these eye malformations 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 women 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 increased risk of developing Attention Deficit Hyperactivity Disorder (ADHD).

iii. What does this mean for me?

Female patients aged under 55 years starting treatment with valproate.

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

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 children who have not yet experienced their first period:**
 - o You/your child should know about the risks of valproate when used during pregnancy.
- **As soon as your child experiences their first period whilst taking valproate:**
 - o You should contact your child's GP who will refer your child to their specialist.
 - o Their specialist will decide with you/your child and another specialist whether their condition does not respond to other treatments and the benefits outweigh the risks and if not, they will try to switch your child to another medicine.
 - o Your child's specialist may ask them to perform a pregnancy test, because they must not take valproate if they are pregnant.
- **Female patients who have started having periods:**
 - o 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.
 - o If you are able to get pregnant your GP or specialist will discuss the need for birth control (contraception) with you/your child.
 - o 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 and with another specialist whether you should continue receiving treatment with valproate or whether another medicine should be prescribed.

I am taking valproate and not planning to have a baby

- If you are taking valproate and do not plan 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 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) you will not be asked to sign the form.

During these visits your specialist will decide with you and with another specialist whether you should continue receiving treatment with valproate or whether another medicine should be prescribed.

I am taking valproate and planning to have a baby

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

- 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. Valproate can harm babies even in early pregnancy.



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

- 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.
- 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:

- Birth defects
- Physical and mental development problems

These can both 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:

- This is to make sure your condition is controlled.
- It is also to check how your baby is developing.



3. Information for male patients

i. What are the risks of taking valproate?

Valproate can potentially cause:

- Male infertility (may be reversible after treatment is stopped or the dose is reduced for some patients).
- Toxic effects on the testes (testicles) of animals - it is unclear what this means for humans.

ii. What does this mean for me?

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

- If you are aged under 55 years, you should only be initiated on valproate if your specialist has discussed with you and another specialist and agreed that your condition does not respond to other treatments or that the risks outlined above do not apply to you. This applies to those aged under 55 years because this is the age group most likely to be affected by the known risk of infertility.
- If you are a patient, parent or a caregiver of a male child treated with valproate,

A specialist will explain to you that there have been studies conducted on animals which suggest it may have an effect on the reproductive system.

At the initial visit with your specialist, you will discuss and sign a Risk Acknowledgement Form to make sure you know and acknowledge the risk of male infertility or toxic effects of valproate on the testes of animals.

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.

Notes

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

**For further copies of this guide please contact Al-Hobail Medical co.
For Medical information, please contact:**

920006647 Ext (110)

Or email

mousa@al-hobail.com

Adverse event reporting

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Please report suspected adverse drug reactions (ADRs) to The National Pharmacovigilance Centre (NPC).

SFDA Call Centre: 19999
Email: npc.drug@sfd.gov.sa
Website:
<https://ade.sfd.gov.sa/>



By reporting adverse drug reactions, you can help provide more information on the safety of this medicine.