

What should I do if I am taking valproate and not planning for pregnancy?

1. You should still use effective contraception during valproate treatment to avoid unintended pregnancy; do not stop using the contraception until your doctor advises you to do so
2. Consult your doctor **AT ONCE** if you think you are pregnant
3. Do not stop taking valproate until you have discussed with your doctor and you are advised to do so

What should I do if I am taking valproate and planning for pregnancy?

1. Consult your doctor first as soon as you have such plan
2. Do not stop using the contraception until your doctor advises you to do so
3. Do not stop taking valproate until you have discussed with your doctor and you are advised to do so

What should I do if I am taking valproate and I find myself pregnant?

1. Contact your clinic **AT ONCE** and schedule an earliest appointment with your doctor if you think you are pregnant
2. Do not stop taking valproate until you have discussed with your doctor and you are advised to do so

The content of this Patient Information Leaflet is developed with reference to the educational materials published by the Medicines and Healthcare products Regulatory Agency (MHRA) and Sanofi (Hong Kong).

The materials could be accessed from below websites:

<https://www.gov.uk/guidance/valproate-use-by-women-and-girls>

<https://www.sanofi.hk/en/healthcare-solutions/declaration/prescription-medicine/mental-health>

**? For any queries,
please seek advice from your doctor,
pharmacist or other healthcare
professionals.**

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Use of Valproate - Contraception and Pregnancy

This applies to all female of childbearing age using valproate, who may get pregnant during treatment.



藥事管理委員會
Drug Management Committee



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Key Information



1. Valproate could be used for treating epilepsy or bipolar disorder
2. Taking valproate during pregnancy can cause serious harm to an unborn child
3. **Always use effective contraception during treatment with valproate**
4. **Do not stop taking valproate** until you have discussed with your doctor and you are advised to do so
5. Consult your doctor as soon as you are planning for pregnancy
6. Contact your clinic **AT ONCE** and schedule an earliest appointment with your doctor if you think you are pregnant

What are the risks of taking valproate during pregnancy?

1. If you take valproate when you are pregnant, it can cause serious harm to your unborn child:
 - The risks are higher with valproate than with other medications for epilepsy or bipolar disorder
 - The risks exist even with smaller doses of valproate - the higher the dose, the higher the risk
2. Taking valproate whilst pregnant can harm your child in two ways:
 - (i) **Birth defects**
 - In women in general population, 2 to 3 babies in every 100 will have a birth defect
 - In women who take valproate while pregnant, around 10 babies in every 100 will have a birth defect
 - Birth defects when the child is born 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

(ii) Development and learning problems

- In women who take valproate while pregnant, 30–40 children in every 100 may have problems with development
- Problems with development and learning as the child grows up include:
 - Delay in learning to walk and talk
 - Intelligence lower 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)

What should I do if I am starting treatment with valproate?

1. Your doctor will explain to you why valproate is considered the right treatment choice for you and all the known possible risks of the treatment
2. If you are too young to become pregnant:
 - Since this could be a life-long treatment, it is important that you and your parents/caregivers know about these risks when valproate is taken during pregnancy. This is so you know what to do when you reach childbearing age and plan to have children
 - You or your parents/caregivers should contact the specialist once you experience menarche during valproate use
3. If you are already at childbearing age:
 - **Always use effective contraception during treatment with valproate**; do not stop using the contraception on your own
4. If you are planning for pregnancy:
 - Consult your doctor first as soon as you have such plan
 - Do not stop taking valproate until you have discussed with your doctor and you are advised to do so

