

Risk acknowledgement form for valproate and risks in pregnancy for girls and women of childbearing potential

Part A – to be completed by a specialist

Read and complete this form when initiating treatment, at annual check-ups, and if a woman is pregnant or plans to become pregnant.

Tick all the boxes in the form to ensure that all risks and information related to the use of valproate during pregnancy have been acknowledged by the patient and/or her parents or guardians.

The prescribing specialist must retain and archive a copy of this completed form with the patient's medical record.

Name of patient or parent/guardian:

I confirm that the above-mentioned patient needs valproate because:

- this patient does not respond adequately to other treatments, or
- this patient is not able to tolerate other treatments

I have discussed the following information with the above-mentioned patient or her parents/guardians:

The overall risks for children exposed to valproate during pregnancy include:

- an approx. 10% chance of birth defects and
- up to a 30 to 40% chance of a wide range of early developmental problems that can lead to learning disabilities.

Valproate must not be used during pregnancy (except in rare cases for patients with epilepsy who are resistant or intolerant to other treatments), and the conditions of the pregnancy prevention programme must be met.

The need for a regular (at least annual) assessment and need to continue valproate treatment, unless otherwise agreed with a specialist.

The need for a negative pregnancy test result when treatment is initiated and repeated as needed (if relevant).

The need for effective contraception, without interruption, throughout entire period of treatment with valproate (if relevant).

The need for the patient to schedule an appointment with a specialist as soon as she plans to become pregnant, to ensure a timely discussion and switch to alternative treatment before contraception is discontinued.

The need for the patient to contact her doctor immediately to assess treatment in the event of suspected or unplanned pregnancy.

I confirm that I have given the patient or her parents/guardians a copy of the Patient Guide.

In case of pregnancy, I confirm that this pregnant patient:

- received the lowest possible effective dose of valproate to minimise possible harm to the foetus
- has been informed of the opportunities for support or counselling, as well as close monitoring of the foetus during pregnancy

Risk acknowledgement form for valproate and risks in pregnancy

Part B – must be given to and completed by the patient or her parents/guardians

Read and complete this form when you see your specialist. This should be done when treatment begins, at annual check-ups, and if you are pregnant or plan to become pregnant.

Tick all the boxes in the form to ensure that all risks and information related to the use of valproate during pregnancy have been discussed and understood.

The prescribing specialist must retain and archive a copy of this completed form with the patient's medical record. One copy of this completed form should be retained by the patient or her parents/guardians.

I have discussed the following with my doctor and I understand:

why I need valproate rather than another medicine

that I should have regular appointments with a specialist (at least once a year) to assess whether valproate remains the best option for me

The risks for children whose mothers took valproate during pregnancy include:

- an approx. 10% chance of birth defects and
- up to a 30 to 40% chance of a wide range of early developmental problems that can lead to significant learning disabilities.

why I must have had a negative pregnancy test when starting treatment, repeated as needed later (if relevant).

that I must always use effective contraception without interruption throughout the entire treatment period with valproate (if relevant).

that I must not stop taking valproate unless my doctor advises me to

that I should consult my doctor as soon as I start planning to become pregnant. This is to make sure I have time to discuss and switch to an alternative form of treatment before I stop using contraception and become pregnant.

that I must schedule an appointment with my doctor as soon as possible if I think I am pregnant

We have discussed the options for effective contraception, or we have planned a consultation with a specialist who has experience in recommending effective contraception.

I have received a copy of the Patient Guide

In the case of pregnancy, I confirm that I have discussed the following with my doctor and understand:

- the opportunities for support and counselling in connection with pregnancy
- the need for close monitoring of my unborn child during pregnancy