ANNUAL RISK ACKNOWLEDGEMENT FORM

Annual Risk Acknowledgement Form for girls and women of childbearing age treated with valproate

Read, complete and sign this form during a visit with the medical practitioner experienced in the management of epilepsy or bipolar disorder: at treatment initiation, at the annual visit, and when a woman plans a pregnancy or is pregnant.

This is to make sure that female patients or their caregiver/legal representative have discussed with the medical practitioner experienced in the management of epilepsy or bipolar disorder and understood the risks related to the use of valproate during pregnancy.

Part A — To be completed and signed by the Prescriber

Name of patient or caregiver/legal representative: _____

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

- this patient does not respond adequately to other treatments or ☐
- this patient does not tolerate other treatments ☐

I have discussed the following information with the above-mentioned patient or caregiver/legal representative:

The overall risks in children exposed to valproate during pregnancy are:

- an approximately 11 % chance of major congenital malformations and ☐
- up to 30 to 40 % chance of a wide range of early developmental problems that can lead to learning difficulties. ☐

Valproate should not be used during pregnancy (except in rare situations for epileptic patients that are resistant or intolerant to other treatments) and conditions of the pregnancy prevention program must be fulfilled. ☐

The need for a regular (at least annual) review by me and the need to continue valproate treatment. ☐

The need for a negative pregnancy test at treatment initiation and as required thereafter (if of childbearing age). ☐

The need for an effective contraception without interruption during the entire duration of treatment with valproate (if childbearing age). ☐

The need to arrange an appointment with me as soon as she is planning pregnancy to ensure timely discussion and switching to alternative treatment options prior to conception and before contraception is discontinued. ☐

The need to contact me immediately for an urgent review of the treatment in case of suspected or inadvertent pregnancy. ☐

I have given the patient or caregiver/legal representative 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 the possible harmful effect on the unborn ☐
- is informed about the possibilities of pregnancy support or counselling and appropriate monitoring of her baby if she is pregnant. ☐

Name of Prescriber _____ **Signature** _____ **Date** _____

This form shall be provided by a medical practitioner experienced in the management of epilepsy or bipolar disorder to girls and women of childbearing age treated with valproate for epilepsy or bipolar disorder (or their caregiver/legal representative).

Parts A and B shall be completed: all boxes shall be ticked, and the form signed. This is to make sure all the risks and information related to the use of valproate during pregnancy have been understood.

A copy of this form completed and signed shall be kept/recorded by the medical practitioner experienced in the management of epilepsy or bipolar disorder.

The prescriber is advised to save an electronic version in the patient dossier. A copy of this form completed and signed shall be kept by the patient.

Annual Risk Acknowledgement Form for girls and women of childbearing age treated with valproate

Read, complete and sign this form during a visit with the medical practitioner experienced in the management of epilepsy or bipolar disorder: at treatment initiation, at the annual visit, and when a woman plans a pregnancy or is pregnant.

This is to make sure that female patients or their caregiver/legal representative have discussed with their specialist and understood the risks related to the use of valproate during pregnancy.

Part B

To be completed and signed by the Patient or caregiver/legal representative.

I have discussed the following with my medical practitioner experienced in the management of epilepsy or bipolar disorder and understand:

- Why I need valproate rather than another medicine. ☐
- That I should visit a **medical practitioner experienced in the management of epilepsy or bipolar disorder** regularly (at least annually) to review whether valproate treatment remains the best option for me. ☐

The risks in children whose mothers took valproate during pregnancy are:

- an approximately an approximately 11 % chance of major congenital malformations (birth defects) and ☐
- up to 30 to 40 % chance of a wide range of early developmental problems that can lead to significant learning difficulties (impaired physical and mental development of the child as it grows after birth). ☐

- Why I need a negative pregnancy test at treatment initiation and if needed thereafter (if of childbearing age). ☐
- That I must use effective contraception without interruption during the entire duration of my treatment with valproate (if of childbearing age). ☐
- We discussed the possibilities of effective contraception, or we planned a consultation with a professional who is experienced in advising on effective contraception. ☐
- The need to consult my medical practitioner experienced in the management of epilepsy or bipolar disorder as soon as I am planning to become pregnant to ensure timely discussion and switching to alternative treatment options prior to conception, and before contraception is discontinued. ☐
- That I should request an **urgent** appointment if I think I am pregnant. ☐
- I have received a copy of the **PATIENT GUIDE**. ☐

In case of a pregnancy, I have discussed the following with my medical practitioner experienced in the management of epilepsy or bipolar disorder and understand:

- The possibilities of pregnancy support or counselling. ☐
- The need for appropriate monitoring of my baby if I am pregnant. ☐

Name of patient or caregiver/legal representative	**Signature**	**Date**

This form shall be provided by a medical practitioner experienced in the management of epilepsy or bipolar disorder to girls and women of childbearing age treated with valproate for epilepsy or bipolar disorder (or their caregiver/legal representative).

Parts A and B shall be completed: all boxes shall be ticked, and the form signed. This is to make sure all the risks and information related to the use of valproate during pregnancy have been understood.

A copy of this form completed and signed shall be kept/recorded by the medical practitioner experienced in the management of epilepsy or bipolar disorder.

The prescriber is advised to save an electronic version in the patient dossier. A copy of this form completed and signed shall be kept by the patient.

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