ANNUAL RISK ACKNOWLEDGEMENT FORM
PART A. TO BE COMPLETED AND SIGNED BY THE PRESCRIBER

Patient name : _____
MRN / ICNo. : _____
Address : _____

For girls and women of childbearing age treated with sodium valproate <Product Name>
Read, complete and sign this form during a visit with the prescriber: at treatment initiation, at the annual visit, and when a woman plans a pregnancy or is pregnant.

Name of patient or care-giver: _____
I confirm that the above-named patient needs sodium valproate because:

☐ *this patient does not respond adequately to other treatments or*

☐ *this patient does not tolerate other treatments*

☐ *that this patient is already stable on ..... dose and she is reluctant to change to other medication.*

☐ *Other reason.....(to specify)*

I have discussed the following information with the above-named patient or care-giver:

☐ *The overall risk to fetus and children whose mothers are exposed to sodium valproate during pregnancy are:*
- *an approximately 10% chance of birth defects and*
- *up to 30 to 40% chance of a wide range of early developmental problems that can lead to learning difficulties.*

☐ *Sodium valproate should not be used during pregnancy (except in rare situations for epileptic patients that are resistant or intolerant to other treatments)*

☐ *The need for regular (at least annually) review and the need to continue sodium valproate treatment by the prescriber.*

☐ *The need for negative pregnancy test at treatment initiation and as required thereafter (if child bearing age).*

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

☐ *The need to arrange an appointment with her doctor 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 her doctor immediately for an urgent review of the treatment in case of suspected or inadvertent pregnancy.*

☐ *In case of pregnancy, I confirm that this pregnant patient:*
• received the lowest possible effective dose of sodium 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:* _____

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

Part A – to be kept by the prescriber

ANNUAL RISK ACKNOWLEDGEMENT FORM
PART B. TO BE COMPLETED BY PRESCRIBER AND SIGNED BY THE PATIENT OR CAREGIVER

Patient name : _____
MRN / ICNo. : _____
Address : _____

For girls and women of childbearing age treated with sodium valproate <Product Name>
Read, complete and sign this form during a visit with the prescriber: at treatment initiation, at the annual visit, and when a woman plans a pregnancy or is pregnant.

I have discussed the following with my doctor and understand:

- ☐ *Why I need sodium sodium valproate rather than other medicine*
- ☐ *I have decided to continue with the treatment after being advised on the risk*
- ☐ *That I should visit the prescriber regularly (at least annually) to review whether sodium valproate treatment remains the best option for me*
- ☐ *The overall risk to fetus and children whose mothers took sodium sodium valproate during pregnancy are:*
  - *an approximately 10% chance of birth defects and*
  - *up to 30 to 40% chance of a wide range of early developmental problems that can lead to significant learning difficulties*
- ☐ *Why I need a negative pregnancy test at treatment initiation and if needed thereafter (if child bearing age)*
- ☐ *That I must use an effective contraception without interruption during the entire duration of my treatment with sodium valproate (if 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 for regular (at least annually) review and the need to continue sodium valproate treatment by the prescriber.*
- ☐ *The need to consult my doctor 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*
- ☐ *In case of a pregnancy, I have discussed the following with my doctor and understand:*
  - *The possibilities of pregnancy support or counselling*
  - *The need to appropriate monitoring of my baby if I am pregnant*

Name of Patient/Caregiver: _____ *Signature:* _____ *Date:* _____

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

Part B shall be completed: all boxes shall be ticked, and the form signed by prescriber and the patient. This is to make sure all the risks and information related to the use of sodium valproate during pregnancy have been understood.
Part B - to be given to patient
- a copy to be kept by the prescriber