Annual Risk Acknowledgement Form

for girls and women of childbearing age treated with valproate
<Mylan-Divalproex (divalproex sodium)>

Read, complete and sign this form during a visit with the specialist: 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 A. To be completed and signed by the Specialist

Name of patient or caregiver/legal representative:

I confirm that the above named 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 named patient or caregiver/legal representative:

The overall risks in children exposed to 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. ☐

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 regular (at least annually) review and the need to continue valproate treatment by a specialist. ☐

The need for negative pregnancy test at treatment initiation and as deemed necessary by the patient or treating physician thereafter (if childbearing age). ☐

The need for the use of at least one effective method of contraception (preferably a user independent form) or two complementary forms of contraception, without interruption, during the entire duration of treatment with valproate (if childbearing age). ☐

The need to arrange an appointment with her physician 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. ☐

I have given the patient or caregiver/legal representative a copy of the patient guide. ☐
More information about valproate use can be found in the Product Monograph (PM).

In case of pregnancy, I confirm that this pregnant patient:
- received the lowest possible effective dose of valproate to minimise possible harmful effects of the drug on the unborn child. ☐
- is informed about the possibilities of pregnancy support or counselling and appropriate monitoring of the baby if she is pregnant. ☐

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Name of the Specialist	Signature	Date

This form shall be provided by a specialist 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 specialist.

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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