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

I have discussed the following with my specialist and understand:

- Why I need valproate rather than another medicine ☐
- That I should visit a specialist 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 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 as deemed necessary by the patient or treating physician thereafter (if childbearing age). ☐
- That I must use 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). ☐
- 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 valproate treatment by a specialist. ☐
- The need to consult my physician 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. **More information about valproate use can be found in the Product Monograph (PM).** ☐

In case of a pregnancy, I have discussed the following with my specialist and understand:

- The possibilities of pregnancy support or counseling ☐
- The need to appropriate monitoring of my baby if I am pregnant ☐

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Name of the patient or caregiver/legal representative	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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