Annual Risk Acknowledgement Form

Annual Risk Acknowledgment Form for girls and women of childbearing age treated with valproate <Depakine>

Read, complete and sign this form during a visit with the Consultant: 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 Consultant and understood the risks related to the use of valproate during pregnancy.

Part A. To be completed and signed by the Consultant

Name of patient or care-giver/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 care-giver/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 required thereafter (if child bearing 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 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 care-giver/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 Consultant Signature Date

This form shall be provided by a Consultant to girls and women of childbearing age treated with valproate for epilepsy (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 Consultant.

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.

For Medical Information:
Please contact: +966 12 2219416
E-mail:ksa.medicalinformation@sanofi.com

For Pharmacovigilance:
Please contact: +966544284797,
Email: ksa_pharmacovigilance@sanofi.com

This risk reduction activity is approved by SFDA

If you have any side effects, please contact :
The National Pharmacovigilance Center (NPC)
Fax: +966-11-205-7662
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/

SASA.VPA.20.02.0100

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Read, complete and sign this form during a visit with the Consultant: 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 Consultant 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 Consultant and understand:

- Why I need valproate rather than another medicine ☐
- That I should visit a Consultant 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 if needed thereafter (if child bearing age) ☐
- That I must use an effective contraception without interruption during the entire duration of my 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 Consultant ☐
- 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. ☐

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

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

Name of patient or caregiver/legal representative Signature Date

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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 Consultant.

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