

Annual Risk Acknowledgement Form

Annual Risk Acknowledgment Form for girls and women of childbearing age treated with valproate (Epilim®, Valpakine®, Depakine®)

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 (signing subject to national implementation)

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 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 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 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 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. Refer to the information about the product inside the box for more information.

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 Specialist

Signature

Date

This form shall be provided by a specialist 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 specialist. Signing and recording subject to national implementation.

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.

This material is part of the risk minimization plan, applies only to patients prescribed with this medication and will be delivered directly by prescribing physician.

For more information, contact the medical department:

In Bolivia, Central America and Caribbean countries:

Sanofi-Aventis de Panamá S.A. Torre Evolution, piso 32, Calle 50 y Av. Aquilino de la Guardia Obarrio-Ciudad de Panamá, República de Panamá Telf.: (507) 382-9500.

infomed.pac@sanofi.com

Web site: <https://www.sanofi-pacifico-caribe.com/es/profesionales-de-la-salud>

For reports of adverse events in the Caribbean and Central America countries: drugs.camwi@sanofi.com

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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 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 (physical and mental development of the child after birth)

Why I need a negative pregnancy test at treatment initiation and if needed thereafter (if childbearing 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 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. For more information about valproate, please refer to <https://www.sanofi-pacifico-caribe.com/>

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

Name of patient or caregiver/legal representative

Signature

Date

This form shall be provided by a specialist to girls and women of childbearing age (or their caregiver/legal representative) treated with valproate for epilepsy.

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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