ANNUAL RISK ACKNOWLEDGEMENT FORM
VALPROATE HAS RISKS IN PREGNANCY

NAME OF VALPROATE USER: _____ DATE OF BIRTH: _____

IDENTIFICATION NUMBER: _____

NAME AND ROLE OF SPECIALIST: _____

SIGNATURE OF SPECIALIST AND DATE: _____

NAME OF VALPROATE USER'S FAMILY DOCTOR: _____

Children exposed to valproate *in utero* have a very high risk of congenital malformations and neurodevelopmental disorders. Valproate should therefore not be used in women of childbearing potential unless the conditions of the Valproate Pregnancy Prevention Program are fulfilled.

The specialist must provide this form to girls and women of childbearing potential treated with valproate (ODAN-VALPROIC ACID,) or to their "responsible person": a parent / legal guardian, or person capable of giving consent on behalf of patients who are minors or without the capacity to make an informed decision or person acknowledging that the treatment is in the best interests of the patient.

THERE ARE THREE STEPS NEEDED TO COMPLETE THIS FORM:

STEP 1 Decide if the patient needs to be on the Valproate Pregnancy Prevention Program.

STEP 2 The Valproate Pregnancy Prevention Program applies to this patient - she is of childbearing potential and at risk of pregnancy.

STEP 3 Your patient needs to complete this section to confirm she understands the risks of valproate in pregnancy.

WARNING:

Prescribing valproate to a woman of childbearing potential without the Valproate Pregnancy Prevention Program conditions being fulfilled represents an unlicensed use of ODAN-VALPROIC ACID. Use of valproate during pregnancy for bipolar disorder, and during pregnancy for epilepsy (unless there is no suitable alternative treatment), are both unlicensed. This is the case even when treatment is based on an informed choice made by the patient. You must document in the patient's clinical record your reason for unlicensed use, that you have informed the patient of the unlicensed use and its associated risk.

THIS FORM EXPIRES ON _____ **(12 MONTHS AFTER COMPLETION).**

COMPLETE A NEW FORM AT EACH ANNUAL REVIEW.

ANNUAL RISK ACKNOWLEDGEMENT FORM
VALPROATE HAS RISKS IN PREGNANCY *(cont)*

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STEP 1

DECIDE IF THE PATIENT NEEDS TO BE ON THE VALPROATE PREGNANCY PREVENTION PROGRAM.

- Women of childbearing potential (from menarche to menopause) who are taking any medicine containing valproate, regardless of the indication, should fulfill all the requirements of the Valproate Pregnancy Prevention Program.
- The only exception is when you (the specialist) consider that there are compelling reasons to indicate that there is no risk of pregnancy.
- The absence of risk of pregnancy may be permanent (e.g. in post-menopausal patients or in patients who have had a hysterectomy), and in this case the risk does not need to be discussed in the next annual review, and the requirements of the Valproate Pregnancy Prevention Program do not apply.
- If the absence of risk is subject to change (e.g. the patient is pre-menarchal), the date for the next annual discussion of the risks must be documented and the patient or the patient's family / caregivers must be asked to contact you promptly if the situation changes before the next annual review in order to bring this review forward.
- Girls who have not yet reached menarche **DO NOT** need to be on the Valproate Pregnancy Prevention Program, but they and their responsible person need to be aware of the risks for the future. You should provide a copy of the Patient Guide and remind the responsible person to contact the specialist or family doctor to arrange for review of treatment as soon as menarche occurs.

If you consider there to be a compelling reason that indicates there is no risk of pregnancy, record it here.
If appropriate, you and your patient should still complete the rest of the form so that your patient and/or her responsible person is aware of the risks if her situation were to change in the future.

TO BE COMPLETED BY THE SPECIALIST WHEN THEY CONSIDER A VALPROATE PREGNANCY PREVENTION PROGRAM IS NOT NEEDED

The requirements of the Valproate Pregnancy Prevention Program are not necessary because there are compelling reasons to indicate that there is no risk of pregnancy, because (check whichever applies):

☐ The patient has not yet reached menarche.
I have informed the patient and family to inform me if this changes before the next annual review, which is due on (insert date):

☐ The absence of pregnancy risk is permanent for the following reason (insert reason):

☐ I consider that sexual activity that could lead to pregnancy will not occur before the next annual review because (insert reason):

☐ I have given the patient or responsible person a copy of the Patient Guide.

SIGNATURE OF PATIENT OR RESPONSIBLE PERSON TO CONFIRM: _____

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VALPROATE HAS RISKS IN PREGNANCY *(cont)*

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STEP 2

THE VALPROATE PREGNANCY PREVENTION PROGRAM APPLIES TO THIS PATIENT- SHE IS OF CHILDBEARING POTENTIAL AND AT RISK OF PREGNANCY

This form confirms that you have discussed the risks with girls, women of childbearing potential and her responsible person (if applicable), and you are acting in compliance with the Valproate Pregnancy Prevention Program.
You need to:

- Explain the risks of valproate in pregnancy and ensure these are understood.
- Give your patient (or her responsible person) a copy of the Patient Guide.
- Complete all parts of this form, keep the original in the patient record, and provide a copy to the patient, her responsible person (if appropriate), and her family doctor / GP.
- Arrange a follow-up appointment at least every year to review the need for continued treatment with valproate and compliance with the Valproate Pregnancy Prevention Program.

TO BE COMPLELED BY THE SPECIALIST	INITIALS
I confirm that the patient needs valproate because: • Her condition does not respond adequately to other treatments, or • She does not tolerate other treatments, or • She is undergoing a treatment change from valproate	
I CONFIRM I HAVE DISCUSSED THE FOLLOWING WITH THE PATIENT:	
Valproate must not be used during pregnancy (except in rare situations in epilepsy for patients who are resistant or intolerant to other treatments)	
The overall risks in children exposed to valproate during pregnancy: • An approximately 10% chance of birth defects • A 30% to 40% chance of a wide range of early developmental problems that can lead to learning disabilities	
The conditions of the Valproate Pregnancy Prevention Program that must be fulfilled	
The need for regular (at least annual) review of the need to continue valproate treatment by a specialist	
The need for effective contraception, without interruption, throughout treatment with valproate	
The need to arrange an appointment with her specialist as soon as she is planning pregnancy to ensure timely discussion and a timely switch to an alternative treatment before stopping contraception and conception occurring	
The need to contact her family doctor / GP immediately for an urgent review of her treatment in case of suspected or inadvertent pregnancy	
The need for a negative (ideally serum) pregnancy test result at start and if needed thereafter	
I CONFIRM I HAVE GIVEN THE PATIENT OR RESPONSIBLE PERSON A COPY OF THE PATIENT GUIDE.	

IN CASE OF PREGNANCY, I CONFIRM THAT:	INITIALS
• We have discussed options for switching treatment, and she is receiving the lowest possible dose.	
• She is fully aware of the risks of pregnancy, has had the opportunity for counselling about the risks, and may need pregnancy support and counselling and appropriate monitoring.	
• I have given the patient or responsible person a copy of the Patient Guide.	

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STEP 3

YOUR PATIENT NEEDS TO COMPLETE THIS SECTION TO CONFIRM THEY UNDERSTAND THE RISKS OF VALPROATE IN PREGNANCY

If you use valproate while you are pregnant, your future child has significant risk of serious harm. Completing this form confirms that you (or your responsible person) understand the risks of using valproate during pregnancy, and what method of contraception you will use to prevent becoming pregnant during treatment.

TO BE INITIALLED AND SIGNED BY THE PATIENT OR HER RESPONSIBLE PERSON	INITIALS
I HAVE DISCUSSED THE FOLLOWING WITH MY DOCTOR, AND I UNDERSTAND:	
Why I need valproate rather than another medicine	
That I should visit a specialist regularly (at least once a year) to review whether valproate remains the best option for me	
That the risks in children whose mothers took valproate during pregnancy are: • 1 out of 10 children will have physical birth defects • 3 to 4 out of 10 children will have early developmental problems that can lead to significant learning disabilities.	
That I have had a pregnancy test (if advised by my doctor / specialist)	
Why I must use effective contraception, without stopping or interruption, at all times while taking valproate	
The options for effective long-term contraception (or a consultation has been planned with a professional who can give me advice)	
The need to consult my specialist or family doctor as soon as I start thinking about becoming pregnant. This is to make sure I have time to switch to another treatment before I come off contraception	
That I should request an urgent family doctor appointment if I think I am pregnant	
I HAVE BEEN GIVEN A COPY OF THE VALPROATE PATIENT GUIDE AND KNOW WHERE TO FIND MORE INFORMATION	

IN CASE OF PREGNANCY, I CONFIRM THAT:	INITIALS
Options for switching treatment have been considered.	
I am fully aware of the risks and have had the opportunity to have counselling about the risks.	
My baby will need appropriate monitoring.	

NAME OF PATIENT: _____

NAME OF RESPONSIBLE PERSON (IF APPLICABLE): _____

SIGNATURE OF PATIENT (OR RESPONSIBLE PERSON): _____ **DATE:** _____

EFFECTIVE CONTRACEPTION IS ESSENTIAL WHILE TAKING VALPROATE.

At least one highly effective method of contraception (preferably a user-independent form such as an intrauterine device or implant) or two complementary forms of contraception, including a barrier method, should be used. Individual circumstances should be evaluated in each case. When choosing the contraception method, involve the patient in the discussion to guarantee her engagement and compliance with the chosen measures. Even in the absence of menstruation, she must follow all the advice on highly effective contraception.