prevent
valproate pregnancy prevention programme

Annual Risk Acknowledgement Form

For girls and women of childbearing age treated with valproate-based medicines (Epilim▼)

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 their parents / legal guardian or caregiver** for patients who are minors or without the capacity to make an informed decision): _____

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 parent/legal guardian/care-giver:

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 who 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 a negative pregnancy test at treatment initiation and as required thereafter (if child bearing age). ☐

The need to use 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, and informed her that information can also be found online at www.medicinesauthority.gov.mt whereby an electronic version of the patient guide, patient card or package leaflet can be obtained. Patient guide, patient card and Annual Risk Acknowledgement Form can be found at www.medicinesauthority.gov.mt/rmm. Enter "Epilim" in the search box and find them under PDF Documents. ☐

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**

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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 medical records. A copy of this form completed and signed shall be kept by the patient.

AUTHORISED BY THE MEDICINES AUTHORITY on 17-FEB-2020

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Annual Risk Acknowledgement Form for girls and women of childbearing age treated with valproate(Epilim)

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 parent/legal guardian/caregiver:

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 if needed thereafter (if child bearing age). ☐

That I must use 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 and understand that I can visit www.medicinesauthority.gov.mt whereby an electronic version of the patient guide, patient card or package leaflet can be obtained. Patient guide, patient card and Annual Risk Acknowledgement Form can be found at www.medicinesauthority.gov.mt/rmm. Enter "Epilim" in the search box and find them under PDF Documents. ☐

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

- The possibilities of pregnancy support or counseling ☐
- The need for 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 specialist.

The prescriber is advised to save an electronic version in the patient medical records. A copy of this form completed and signed shall be kept by the patient.

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