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V1.00 - 05/2020

PRESCRIBING CHECKLIST & CONSENT FOR VALPROATE IN WOMEN & GIRLS

<p>PRESCRIBING CHECKLIST & CONSENT FOR VALPROATE USE IN WOMEN & GIRLS (for consumers and prescribers)</p>	<p style="text-align: right;">(Affix patient identification label here)</p> <p>URN: _____</p> <p>Family Name: _____</p> <p>Given Names: _____</p> <p>Address: _____</p> <p>Date of Birth: _____ Sex: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> I</p>
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PRESCRIBING CHECKLIST FOR VALPROATE

The following checklist helps ensure that the epilepsy patient, their partner and relevant family members and their legal guardian (where relevant):

- have been informed about the use of valproate while planning, during and after a pregnancy,
- understand the information provided to them, and
- agrees that there has been a shared discussion between them and their treating neurologist regarding the risks and benefits of taking valproate during the patient's child-bearing years.

This information may change over time. Please remember to discuss this regularly, at least yearly, with your doctor. If you have any questions or concerns about the information provided to you, you should discuss this with your doctor at any time.

**This form is part of a shared decision-making process regarding the use of valproate.
To be discussed, completed and signed by the patient (and/or legal guardian) and the prescriber.**

Name of patient: _____ Date of birth: ____ / ____ / ____

The patient's diagnosis: _____

For the purpose of this document, reference to "patient" includes the patient's legal guardian.

Commitment by Neurologist

I, (name of doctor) _____ confirm that to the best of my ability and knowledge, I:

- a) have provided to the patient the brochure: *Valproate and Women* and given the patient adequate time to read that brochure,
- b) have assessed that the patient did not need the assistance of an interpreter,
- c) have discussed with the patient the information contained in the brochure: *Valproate and Women*
- d) believe the patient understood the information contained in that brochure,
- e) believe that the above-named patient needs valproate because she has a generalised form of epilepsy that is not adequately treated by one or more other anti-epileptic drugs. Yes No
- f) provide the following information about the patient's condition, which was discussed with the patient

Previous treatments trialled and reasons for discontinuation:

Current valproate dose: _____

The reasons for the current dose are: _____

Was valproate used in combination with lamotrigine or other anti-epileptic drugs? Yes No

If so, which other drugs were used in combination with valproate? _____

Do the risks of not being on valproate outweigh the risks to a potential unborn child? Yes No

Risks if not on valproate are: _____

(Affix patient identification label here)

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URN:

Family Name:

Given Names:

Address:

Date of Birth:

Sex: M F I

Considerations prior to commencement of valproate

- Folic acid supplementation Discussed
- Consideration of pregnancy test Discussed
- Importance of adequate contraception Discussed

Including explaining that effective contraception is essential while taking valproate, neither condoms nor oral contraceptives alone are recommended, and that long-term contraceptives are strongly recommended.

Highly effective contraception is a user-independent method (long-acting reversible contraceptives) such as:

- Copper intrauterine device (Cu-IUD)
- Levonorgestrel intrauterine system [Mirena ®]
- Progestogen-only implant [Implanon®]
- Long-acting progesterone injections (Depo Provera) Discussed

If user-independent method is not chosen, two complementary forms of contraception should be considered Discussed

Consultation with GP or gynaecologist recommended Discussed

Summary of currently known risks in unborn children where their mother uses valproate

1. Valproate has been shown to increase risks of organ and limb abnormalities in the unborn child. This is a dose-dependent risk.
2. Increased risk of the child having lower intelligence has been reported.
3. Increased risk of the child having an Autism Spectrum Disorder. Discussed

Ongoing patient review whilst on valproate (non-pregnant and of child bearing age)

1. Review with the patient's neurologist is required at least once a year whilst on valproate.
2. If pregnancy is planned, the patient should make an appointment with their neurologist as soon as possible. (Including switching to an alternative treatment before falling pregnant or before stopping contraception). Discussed

UNPLANNED pregnancy on valproate.

1. If the patient becomes pregnant she must immediately seek advice from her treating neurologist and General Practitioner.
2. Even if pregnant, anti-epileptic drugs should not be abruptly stopped, as there is a risk of seizures.
3. The risk period for organ and limb abnormalities in the unborn child is in the first twelve weeks of the pregnancy, but the risk of the child having lower intelligence and or developing an autism spectrum disorder will probably last for the entire pregnancy.
4. Discussion with the treating neurologist
 - a) Does the patient need to continue valproate?
 - b) Can valproate dose be reduced
 - c) Can another anti-epileptic drug be used?
 - d) What does the research show for other anti-epileptic drugs the patient may be able to use?
5. Individual instructions:

.....
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..... Discussed

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(Affix patient identification label here)

URN:
Family Name:
Given Names:
Address:
Date of Birth: Sex: M F I

I (Prescriber) acknowledge and agree that I have discussed and explained the above information to the patient (and legal guardian where relevant).

Name of prescriber:

Signature: Date: / /

Note: Should be signed in presence of patient or guardian, and on the same date as when patient signs

Commitment by Patient:

The patient (or legal guardian if relevant, on behalf of the patient) acknowledges:

- Depending on the patient's sexual activity, given the patient's age there is a possibility that she could fall pregnant,
- I have been provided with the details for contacting Epilepsy Queensland, where I can obtain further information and resources I have been provided with, and read the brochure *Valproate and Women*,
- I have discussed with the doctor who prescribes valproate, and understand the information in, the brochure *Valproate and Women*,
- In particular I have discussed with the doctor who prescribes valproate and understand the:
 - risks of continuing valproate
 - risks of changing the dose of valproate
 - risks of damage to an unborn child if taking valproate while pregnant
 - importance of using effective contraception if the patient does not want to become pregnant and is taking valproate;
- (For a patient with legal capacity) If it appears that I may be pregnant I will seek an urgent appointment with my GP and neurologist,
- (For a patient with legal capacity) If I want to become pregnant, I will seek an appointment with my GP and neurologist as soon as possible to discuss how to safely become pregnant,
- (For a patient with an appointed guardian) If it appears the patient may be pregnant I, as legal guardian, will seek an urgent appointment with the patient's GP and neurologist,
- (For a patient with an appointed guardian) If the patient wants to become pregnant, I will seek an appointment with the patient's GP and neurologist as soon as possible to discuss how the patient may safely become pregnant.

Name of patient:

Signature of patient (if patient has capacity to sign): Date: / /

If a legal guardian has been appointed,

Name of legal guardian:

Signature of legal guardian: Date: / /

*The original signed form shall be uploaded into ieMR patient notes.
Provide copy of this completed form to the GP
Provide copy of this completed form to the patient, and where relevant to their legal guardian or other person capable of giving consent on behalf of patients who do not have the capacity to make an informed decision.*

This form expires 12 months from this date. A new form should be completed at each annual review.