Physician Checklist

Physician Checklist for girls and women of childbearing age treated with valproate (Depalept Chrono)

As part of the regular risk assessment carried out by the specialist, this form must be read and completed 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 the risks related to the use of valproate during pregnancy.

To be completed by the Specialist

Name of patient or care-giver/legal representative:

I confirm that the above named patient needs valproate because there are no suitable alternative treatments (e.g. this patient does not respond adequately to other treatments, this patient does not tolerate other treatments, this patient has a condition for which there are no adequate alternative 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 child..... ☐
  - is informed about the risks to the unborn child and the patient herself of untreated epilepsy
  - is informed about the possibilities of pregnancy support or counselling and appropriate monitoring of her baby if she is pregnant

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The specialist must keep and be able to produce a copy of this form once it has been completed. The prescribing doctor is recommended to keep an electronic version of this form in the patient's file.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions in the Ministry of Health Portal: https://sideeffects.health.gov.il/

Additionally should be reported to Sanofi Israel Pharmacovigilance: PV.Israel@sanofi.com

The Ministry of Health has approved the format and the content of the Physician Checklist in November 2020.