



Valproate: updates to the HCP and patient guides

This is a reminder on the **important safety information** with regards to the use of Epilim® (Sodium Valproate), and the corresponding Valproate HCP and Patient Guides, which is in accordance with the Epilim® prescribing information that had been approved by the Health Sciences Authority (HSA), Singapore, available on the HSA website.

Information related to the risks of abnormal pregnancy outcomes in children exposed to valproate in utero, with new information on the risk of hearing impairment or deafness, updates related to the risk of ADHD have been included in these guides.

For more details on the information on valproate as mentioned, please refer to the following documents which can be found at <https://www.campus.sanofi.sg/products/epilim>

- HCP Guide
- Patient Guide
- Patient Card
- Annual Risk Assessment Form

<p>GUIDE FOR HEALTHCARE PROFESSIONALS</p> <p>Information on the risks of valproate (Epilim®) use in female patients and pregnant women.</p> <p>Contraception and pregnancy prevention</p>	<p>Annual Risk Acknowledgement Form</p> <p>Annual Risk Acknowledgement Form for girls and women of childbearing age treated with valproate <Epilim®></p> <p>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.</p> <p>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.</p> <p>Part A. To be completed and signed by the Specialist</p> <p>Name of patient or care-giver/legal representative:</p> <p>I confirm that the above named patient needs valproate because:</p> <ul style="list-style-type: none">• this patient does not respond adequately to other treatments or <input type="checkbox"/>• this patient does not tolerate other treatments <input type="checkbox"/>
<p>Patient Guide</p> <p>Valproate* (Epilim®) Contraception and Pregnancy: what you should know</p> <p>Patient Guide</p> <p>This booklet is for you if you are a girl or a woman taking any medicine containing valproate (or your caregiver/legal representative).</p> <p>It is a risk minimization measure part of the valproate Pregnancy Prevention Program aiming to minimize pregnancy exposure during treatment with valproate.</p> <p>It contains key information about the risk of valproate use during pregnancy.</p> <p><small>*Valproate is also known as Epilim®</small></p>	<p>Patient Card</p> <p>Patient Card for Valproate <Epilim®>: Contraception and Pregnancy</p> <p>What you must know *</p> <ul style="list-style-type: none">• Valproate is an effective medicine for epilepsy and bipolar disorder.• Valproate can seriously harm an unborn child when taken during pregnancy.• Always use effective contraception without interruption during the entire duration of treatment with valproate.• Remember to visit your specialist at least each year. <p><small>*This applies to all girls and women using valproate and who could become pregnant. Keep this card safe so you always know what to do. MAT-SG-2000113-1.0-08/2021</small></p>

Call for reporting

Any suspected adverse events should be reported to the Health Sciences Authority (HSA), Singapore via the online adverse event reporting form available at <https://www.hsa.gov.sg/>

Company contact point

Adverse drug reactions should also be reported to Sanofi-Aventis (Singapore) Pte Ltd, pharmacovigilance mailbox PV.SIN@sanofi.com

For further medical information on Epilim®, please contact Sanofi-Aventis (Singapore) Pte Ltd medical enquiry mailbox Med.SAMS@sanofi.com with the subject title "EPILIM".