

17 September 2025

Updated safety information for valproate: Risk in pregnancy and women of childbearing potential - lower birth weight following *in utero* exposure to valproate

Dear Healthcare Professional,

This letter is sent in agreement with Medsafe, to inform you of new safety information relating to the use of valproate (Epilim) in pregnancy and women of childbearing potential. Sanofi would like to remind you that valproate should not be used in female children and women of childbearing potential unless other treatments are ineffective or not tolerated.

Further, valproate is contraindicated in the following situations:

Treatment of epilepsy

- In pregnancy unless there is no suitable alternative treatment
- In women of childbearing potential, unless the physician has provided information in regards to the potential effects of valproate during pregnancy and recommendations on the use of valproate

Treatment of bipolar disorder

- In pregnancy
- In women of childbearing potential, unless the physician has provided information in regards to the potential effects of valproate during pregnancy and recommendations on the use of valproate

SUMMARY OF CHANGES TO THE DATA SHEET

| Section Changed | Summary of New Information |
|-----------------|---|
| 4.4 | Updated to add risk of lower birth weight for the gestational age for children exposed to valproate <i>in utero</i> . |
| 4.6 | Updated to add risk of lower birth weight for the gestational age for children exposed to valproate <i>in utero</i> . |

EDUCATIONAL MATERIALS

Revised Educational Materials have been developed to inform HCPs and female patients on the risk of lower birth weight for the gestational age for children exposed to valproate *in utero*.

- [Updated Valproate Female Patient Guide](#)
- [Updated Valproate HCP Guide](#)



Copies of these materials are accessible via: <https://qr.medsinfo.com.au/tx/sw.cfm?h=swcepili> or the QR code on the carton.

CALL FOR REPORTING

Please remember that any suspected adverse events should be reported to [Medsafe](#).

COMPANY CONTACT

Adverse reactions can also be reported directly to Sanofi: email ae@sanofi.com or phone 0800 283 684. Our medical information department can be contacted for further information at medinfo.australia@sanofi.com or 0800 283 684.

Please review the full Data Sheet before prescribing:

Epilim: <https://www.medsafe.govt.nz/profs/Datasheet/e/Epilimtabsyrliqiv.pdf>

Epilim IV: <https://www.medsafe.govt.nz/profs/Datasheet/e/EpilimIV.pdf>

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| Funding Status: Epilim is fully funded |
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Yours faithfully,

James Scott
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