

Important Update – Discontinuation of EPILIM® (sodium valproate) Crushable Tablets 100 mg and New Safety Information for Valproate - lower birth weight following in utero exposure to valproate

Dear Healthcare Professional,

Discontinuation of EPILIM® Crushable Tablets 100 mg

We wish to inform you that EPILIM® (sodium valproate) Crushable Tablets 100 mg will be delisted from the Pharmaceutical Benefits Scheme (PBS) and deregistered from the ARTG. This is due to a global decision to discontinue EPILIM® Crushable Tablets and not related to the quality or safety of the product.

Product	AUST R Number	Anticipated Delisting Date
EPILIM® Crushable Tablets 100 mg	15373	28 Feb 2026

Please note, that all other EPILIM® oral formulations will remain available, including EPILIM® Sugar Free Liquid 200 mg/5mL, EPILIM® Syrup 200 mg/5mL and EPILIM® Enteric Coated Tablets (200 mg and 500 mg). To ensure patients currently on EPILIM® Crushable Tablets 100 mg continue to receive appropriate treatment, we encourage you to switch them to an alternative formulation as soon as practical.

We apologise for the inconvenience this may cause, and we thank you for your assistance in discussing suitable alternatives with your patients.

Updated Safety Information – Valproate Use in Pregnancy

We wish to inform you of new safety information relating to the use of valproate 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 mania

- 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 PRODUCT INFORMATION

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 in utero.
4.6	Updated to add risk of lower birth weight for the gestational age for children exposed to valproate in utero.
