

**Important Information relating to the Epilim Range of Products -  
Pregnancy Prevention**

March 12th, 2020

Dear Pharmacist,

Following an EU review of sodium valproate-containing medicines, updates to the product information for the Epilim range of products were approved by the HPRA regarding the requirements for a pregnancy prevention plan. These updates included changes to the package leaflets, the inclusion of a pregnancy warning symbol on the blister packs, and a pregnancy warning symbol and an updated text warning on the outer cartons.

The HPRA is aware that there are some legacy batches of Epilim products remaining on the Irish market which, although released in compliance with the relevant marketing authorisations at the time, do not contain the updates required after the 2018 review. Some of these batches have expiry dates into late 2020 and early 2021.

The following Epilim batches may still be in pharmacies and they do not carry all of the most up-to-date information in relation to pregnancy prevention:

<b>Product</b>	<b>PA No.</b>	<b>Batch No.</b>	<b>Expiry date</b>
Epilim 100mg Crushable Tablets	PA540/150/001	7R019	31.10.2020
Epilim Enteric 200 mg gastro-resistant coated tablets	PA540/150/002	7R037	30.09.2020
Epilim Enteric 500mg Gastro-resistant Coated Tablets	PA540/150/003	8R003	31.01.2021
Epilim Chrono 200mg Prolonged Release Tablets	PA540/150/010	7A221	31.12.2020
Epilim Chrono 300mg Prolonged Release Tablets	PA540/150/011	8A300	31.01.2021
Epilim Chrono 500mg Prolonged Release Tablets	PA540/150/012	8A514	31.01.2021
Epilim Chrono 500mg Prolonged Release Tablets	PA540/150/012	7A533	30.04.2020
Epilim Intravenous 400mg powder and solvent for solution for injection or infusion	PA540/150/013	A7816	31.10.2020
Epilim Intravenous 400mg powder and solvent for solution for injection or infusion	PA540/150/013	A7767	31.03.2020
Epilim Syrup 200mg/5ml Oral Solution	PA540/150/015	303	31.03.2021
Epilim Syrup 200mg/5ml Oral Solution	PA540/150/015	289	30.04.2020

The HPRA wishes to highlight the existence of these batches to pharmacists. This is so that pharmacists may take measures to ensure that any woman/girl of childbearing potential who is being dispensed Epilim receives the most up-to-date information about their medicine, specifically in relation to pregnancy prevention.

- If you are dispensing any of the above listed Epilim products, please check if the batch number on the pack you have is listed above.
- If it is listed above, please ensure that your patient receives a copy of the latest package leaflet for that Epilim product at the time of dispensing – the most up-to-date package leaflet is available on the HPRA website ([www.hpra.ie](http://www.hpra.ie)) in the *Find a Medicine* section. It can be printed and given to the patient.
- There are pharmacy warning stickers available from Sanofi (the Marketing Authorisation Holder for Epilim) which were provided for situations where broken bulk dispensing cannot be avoided. These stickers contain the pregnancy warning symbol and could be utilised at the time of dispensing for those batches that do not display the pregnancy warning symbol on the outer pack. We understand that they were distributed to pharmacies by Sanofi in May 2018 and February 2020. They may be ordered from Sanofi by contacting Sanofi Medical Information on Tel: (01) 403 5600 or e-mail: [IMedinfo@sanofi.com](mailto:IMedinfo@sanofi.com). The pharmacy warning stickers are also available to print from the HPRA website, at [http://www.hpra.ie/homepage/medicines/special-topics/valproate-\(epilim\)/educational-materials-toolkit](http://www.hpra.ie/homepage/medicines/special-topics/valproate-(epilim)/educational-materials-toolkit).
- An Epilim patient card is also available from Sanofi – it also was distributed to pharmacies in May 2018 and February 2020. It may also be printed from the above HPRA website location. These cards should be given to all women/girls of childbearing potential who are being dispensed Epilim.
- There are various other risk mitigation measure materials available on the HPRA website, as the same location as above.

The HPRA appreciates your assistance with the above. Thank you. Kind regards,

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Kevin O'Donnell, PhD,  
Market Compliance Manager, HPRA  
[kevin.odonnell@hpra.ie](mailto:kevin.odonnell@hpra.ie)