



Dear Pharmacist,

## VALPROATE PREGNANCY PREVENTION PROGRAMME

We are writing to remind you of the importance of the Valproate Pregnancy Prevention Programme which was communicated in April 2018. Patient groups have brought to our attention that women are still not being made aware of the risks of taking valproate medicines during pregnancy. Pharmacies should now have received packs of educational materials for healthcare professionals and for patients. Further information on actions required was given to GPs, specialists, and dispensers in the September Drug Safety Update <https://www.gov.uk/drug-safety-update/valproate-pregnancy-prevention-programme-actions-required-now-from-gps-specialists-and-dispensers>

In addition to giving patients the patient booklet and patient card from the educational materials, it is also important that they receive the statutory patient information leaflet which contains details of the risks associated with valproate medicines. Manufacturers' packs ("original packs") will contain leaflets with the warnings about use in pregnancy. However, we have been given evidence that when bulk product is being broken down and supplied in pharmacy boxes ("white boxes"), they often do not contain the Patient Information Leaflet. Given the serious risk of harm with valproate being used in pregnancy, the Patient Information Leaflet should always be provided with this medicine, even when dispensed in a pharmacy box.

If pharmacists or pharmacies require additional patient information leaflets for valproate, they may photocopy the leaflet from the bulk product or download them from the following sites, together with the risk materials:

MHRA <https://www.gov.uk/guidance/valproate-use-by-women-and-girls>

eMC <https://www.medicines.org.uk/emc/>

Sanofi <http://www.sanofi.co.uk/l/gb/en/layout.jsp?scat=7CF435AE-4B79-4FDE-837B-3AFA25D76B2F>

For hard copies of all the information contact Sanofi medical information department on 0845 372 7101 or email [UK-Medicalinformation@sanofi.com](mailto:UK-Medicalinformation@sanofi.com).

Valproate must no longer be used in any woman or girl able to have children unless she has a pregnancy prevention programme in place. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant. We expect all healthcare professionals, including pharmacists, to ensure that this is the case for their patients.

Yours faithfully,

Dr Ian Hudson  
Chief Executive  
Medicines and Healthcare products Regulatory Agency

This letter has been signed by the UK Chief Pharmaceutical Officers.

Dr Keith Ridge  
Department of Health  
and Social Care

Dr Mark Timoney  
Department of Health,  
Northern Ireland

Dr Rose Marie Parr  
Scottish Government

Andrew Evans  
Welsh Government



Department  
of Health &  
Social Care



Department of  
**Health**

An Roinn Sláinte  
Mánnystrie O Poustie



**The Scottish  
Government**  
Riaghaltas na h-Alba



Llywodraeth Cymru  
Welsh Government