

Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 1
From:	Andrew Evans, Directorate of Health Policy
Date:	23 October 2018
Reference:	CEM/CPhA/2018/16c
Category:	Action within 48 hours
Title:	Valproate Pregnancy Prevention Programme – An Update For Pharmacists
What is this about:	
Why has it been sent:	For your information and to pass on to Colleagues

Issue:

In April 2018 an alert was issued relating to the Valproate Pregnancy Prevention Programme. We are issuing the attached information to pharmacists to remind them of the resources available, including statutory patient information leaflets and the importance of making these available to patients.

This letter should be shared with all pharmacists within your organisation.

To: NHS Wales Shared Services Partnership to forward to:

All General practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.

All Community Pharmacists

Deputising services

HB Chief Pharmacists

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales

To: Chief Executives of Health Boards

To: Medical Directors of Health Boards

To: Nurse Directors Health Boards

To: Directors of Public Health

To: Hospital Principals and Chief Pharmacists to action as per alert

cc: Public Health Wales

Consultants in Pharmaceutical Public Health

Chief Executives, NHS Trusts

Principal Pharmacist Welsh Quality Control

Principal Pharmacist Continuing Care Services

Principal Pharmacist Welsh Medicines Information Centre

CSSIW

NHS Direct



Medicines & Healthcare products
Regulatory Agency



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/lq/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.

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
Máinnstríe O Poustie



The Scottish
Government
Riaghaltas na h-Alba



Llywodraeth Cymru
Welsh Government