NHS Greater Glasgow & Clyde

Interim Risk Assessment for Community Pharmacy

Exception to Requirement to Dispense Valproate in Original Packs

Since 11/10/23 the MHRA provided updated guidance on original pack dispensing of any preparation containing valproate to ensure all the relevant safety information is available to patients. This applies to both male and female patients. In appropriate cases, pharmacists can make an exception to the requirement to dispense full packs, on an individual patient basis.

Not dispensing in an original pack (OP) may be necessary if daily/weekly dispensing or blister packing is required or the patient is at risk of overdose and smaller supplies are required on safety grounds.

Protocol

1. Any requests for a compliance device or other weekly/daily dispensing that include any valproate preparation should be risk assessed by the pharmacist.
2. Where original pack dispensing of valproate is assessed as inappropriate, the risk assessment form below must be completed. The form need only be completed once for each patient.
3. Completed risk assessments should be stored in accordance with NHS Scotland retention periods.
4. If non - OP dispensing is necessary; for female patients, dispensary teams should ALWAYS provide a copy of the package leaflet, the patient card **and** add a valproate warning sticker to the outer box (es).
5. If non –OP dispensing is necessary; for male patients, dispensary teams should ALWAYS provide a copy of the package leaflet.

The risk assessment form must be tailored/prepared and approved/signed off by the superintendent pharmacist /pharmacy contractor before being used/implemented. This should be reviewed regularly and following any significant incident or change to the service.

Produced by NHSGGC Community Pharmacy Development Team
Approved by NHSGGC Valproate Safety Stakeholders Group
Date approved: March 2024
Version: V1

NHS Greater Glasgow & Clyde

Interim Risk Assessment for Community Pharmacy

Exception to Requirement to Dispense Valproate in Original Packs

VALPROATE RISK ASSESSMENT
Patient Name:_____ **CHI:** _____

Patient address:_____ **GP Practice:**_____

Risk associated with supplying in manufacturer's original packaging (tick all that apply)

Patient may take too many or too few doses (or none at all)	
Patient has memory problems/confused	
Patient unable to open original packaging	
Risk of self-harm/suicide; patient being prescribed daily/weekly	
Other risk (please detail)	

Decision

Supply in original packaging? YES/NO

If NO, i.e not being supplied in original packaging, what is the reason for the exception to national guidance?

- Patient supplied medication in a monitored dosage system (MDS)/compliance aid to ensure safe compliance ☐
- Risk of overdose/self-harm, and it would not be safe to have an original pack quantity in the home ☐
- Other reason the patient is unable to manage valproate separately (please state): …… ☐

When will the patient need to be reassessed? As a minimum this should be repeated annually - individual patient factors/changes will need to be considered	Date……..

Add any additional comments in box:

Risk Assessment Completed by: ……

Signature: …… **Date:** ……

Produced by NHSGGC Community Pharmacy Development Team
Approved by NHSGGC Valproate Safety Stakeholders Group
Date approved: March 2024
Version: V1