# Original pack dispensing of valproate exceptions risk assessment

## Background

Valproate is a treatment for epilepsy and mental health conditions such as bipolar disorder. Valproate-containing medicines are sodium valproate, valproic acid and valproate semi-sodium. There is a significant risk of birth defects for unborn babies and developmental disorders in children born to women who take valproate-containing medicines during pregnancy. Because of these risks, women and girls of childbearing potential must fulfil the conditions of the Valproate Pregnancy Prevention Programme which is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant. For more information about the risks of valproate-containing medicines in pregnancy see the Medicines and Healthcare products Regulatory Agency (MHRA)’s [Valproate use in women and girls page](https://www.gov.uk/guidance/valproate-use-by-women-and-girls).

The manufacturers’ original full pack for valproate-containing medicines includes specific warnings and pictograms, including a patient card and the Patient Information Leaflet. These documents alert patients to the risks to unborn babies if valproate is used in pregnancy. From 11th October 2023, following a [consultation](https://www.gov.uk/government/consultations/original-pack-dispensing-and-supply-of-medicines-containing-sodium-valproate/original-pack-dispensing-and-supply-of-medicines-containing-sodium-valproate), the Government amended the Human Medicines Regulations 2012 [(HMRs)](https://www.gov.uk/government/publications/full-pack-dispensing-of-valproate-containing-medicines/full-pack-dispensing-of-valproate-containing-medicines) to:

* require manufacturer’s original full pack dispensing of valproate-containing medicines.
* enable pharmacists to supply up to 10% more than or less than the amount on a prescription of medicines other than those containing valproate, so that they can dispense a manufacturer’s original full pack instead of splitting the pack, known as original pack dispensing (OPD). Unless an exceptional circumstance (see below), pharmacists may either round up or down so that the patient receives their supply in the **manufacturer’s original full pack** and ensure that they receive an amount that is as close as possible to that prescribed. Pharmacists must not subsequently re-package any valproate-containing medicine into plain dispensing packaging.

**Unless there are exceptional circumstances (see Appendix 1 below), valproate-containing medicines must always be dispensed in the manufacturer’s original full pack from 11 October 2023.**

The manufacturer’s original full pack does not have to be supplied where:

(i) a **risk assessment** is in place that refers to the need for the patient to be sold or supplied valproate-containing medicines in different packaging from its manufacturer’s original full outer packaging (for example, in a monitored dosage system) and

(ii) assuming that the product is authorised, there are processes in place to make sure that the patient receives the **Patient Information Leaflet**. That is not the case for unauthorised medicines, unless they are only unauthorised as a result of an assembly process.

**Appendix 1 Original pack dispensing of valproate exceptions**

**Risk Assessment**

(*For exceptional circumstances when considering to supply valproate not in an original full pack*)

If a patient needs to have a supply of valproate *not in an original pack*, then a risk assessment **MUST** be undertaken by the most appropriate healthcare professional using their professional judgement to ensure a supply can be issued safely and the patient is aware of the risks associated with valproate medications.

**This assessment should be done by an appropriate healthcare professional prior to dispensing the prescription either at the time of discharge or following an outpatient appointment from secondary care, or when a repeat prescription is requested in primary care.**

* The outcome of the risk assessment should be documented clearly in the patient’s clinical records and/ or the discharge summary and clinic letter. The risk assessment should also be **shared** with the patient’s community pharmacy (if they are not undertaking the assessment).

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| **VALPROATE RISK ASSESSMENT**  **Patient Name: ………………………………..…..….. Patient Date of Birth: ………………………………………………..**  **Patient address: ……………………………………... Patient’s GP Practice: ……………………………………….……….** | |
| Can the patient be supplied with valproate in an original pack? | YES/NO |
| **If no,** what is the reason for the exception to national guidance:   * Risk of overdose/self-harm, and it would not be safe to have an original pack quantity in the home □ * Patient on short term leave from hospital □ * Patient does not understand what the medicine is for, or how to take it correctly or suffers from confusion / has memory problems □ * Other reason the patient is unable to manage valproate in an original pack (please state): …………………………………………………………………………………. □   Valproate is not recommended in a monitored dosage system - Please refer to [BNSSG](https://remedy.bnssg.icb.nhs.uk/formulary-adult/local-guidelines/19-other/) / [AHSN](https://www.healthinnowest.net/our-work/transforming-services-and-systems/medicines-optimisation/medicines-compliance-aids-mcas/) guidance and SPS [MCA stability Tool](https://www.sps.nhs.uk/home/tools/medicines-in-compliance-aids-stability-tool/) for valproate stability information if considering a compliance aid. | |
| When will the patient need to be reassessed? (individual patient factors will need to be considered) | Date  ….….…………... |
| Has the patient been given a Patient Information Leaflet (PIL)?  How has the patient been given a patient information leaflet (PIL)? **This is a requirement if an original pack is not supplied.** **The pharmacist should be satisfied processes are in place to ensure the supply to or for the patient of the information leaflet at the point of assessment.** | YES/NO  ………………….. |

#### Add any additional comments in box:

***If the patient cannot have valproate in an original pack:***

* Appropriate Healthcare Professional completing the risk assessment should ensure the patient receives a patient information leaflet outlining the risks following the completion of a risk assessment.

**Risk Assessment Completed by:** ………………………… **Signature:** …………………………..…. **Date:** …………………….

**Job Title:** ……………………………………………………………... **Registration number** (if applicable): …….……………………

***Note:*** *It is advisable to review and update the risk assessment periodically (for example, there are changes in the patient’s circumstances). Advise patients to proactively inform the pharmacy if their circumstances change.*