PDSPN Guide to support Professional judgement when Considering Inclusion of Madopar® Preparations in Compliance Aids

This guidance document is to support pharmacy professionals to apply professional judgment when considering inclusion of Madopar® preparations in compliance aids as part of the dispensing process

It is important to note that the inclusion of any **Madopar®** preparations in compliance aids would be **considered off-licence.** Other medications in compliance aids which may affect the stability should also be taken into account. Nevertheless, concerns about including Madopar® in compliance aids should be balanced against any potential **clinical consequences for the individual situation**, such as the risk of patients **not taking their medication** and a **loss of control** of their **Parkinson's symptoms.**

The Parkinson's Disease Specialist Pharmacist Network (PDSPN) has received multiple queries regarding the use of Madopar® preparations in compliance aids. The PDSPN has been in contact with the manufacturer, the Specialist Pharmacy service (SPS) and medicines information (MI) departments and has compiled the guidance below.

'The current recommendation from the SPS[1] in the Medicines in Compliance Aids Stability Tool states that **all Madopar® formulations are incompatible in compliance aids**. This recommendation is derived from the manufacturer, Roche, who can only guarantee the stability of Madopar® products in the original container at the recommended storage conditions.

However, previous recommendations from SPS (2015)[2] state that **Madopar® CR 100 mg/25 mg Prolonged Release Hard Capsules** and **Madopar® 50 mg/12.5 mg, 100mg/25mg, 200mg/50mg Hard Capsules** are **stable in a compliance aid for a maximum of 7 days**. It has been confirmed with Roche, that the formulation of Madopar® products has not changed since this advice was produced. Therefore, since there have been no changes in formulation to Madopar® products, this advice remains relevant for including Madopar® hard capsules in compliance aids with a 7-day expiry date.

Previous recommendations from SPS (2015)[2] state that **Madopar® 50 mg/12.5 mg and 100 mg/25 mg Dispersible Tablets** are **not suitable for compliance aids.** However, in one study by **Albert et al (2017)[3]**, found that after four weeks at room temperature Madopar® tablets showed no **visible** alterations when re-packaged**. However, no chemical analyses were undertaken to confirm this hypothesis.** Whilst the trial did not detect any visual alteration, we have no data to support that the efficacy was not affected so we must rely on patient/carer feedback to ensure there are no changes to the patient's Parkinson's symptoms which could indicate that the **Madopar® Dispersible Tablets** have had a measurable level of degradation. Therefore, **we do not recommend including Madopar® Dispersible Tablets in a compliance aid unless the benefits strongly outweigh the risks.'**

In summary, as the manufacturer confirms that there have been no changes to the formulation of Madopar® preparations, Madopar® CR 100 mg/25 mg Prolonged Release Hard Capsules and Madopar® 50 mg/12.5 mg, 100mg/25mg, 200mg/50mg Hard Capsules are considered to be stable in a compliance aid for a maximum of 7 days. There are no data for generic formulations of Co-Beneldopa (Levodopa/Benserazide).

Information is correct as of March 2025.

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[1]1. 'Specialist Pharmacy Service, 2025, MCA Stability Tool. https://www.sps.nhs.uk/home/tools/medicines-in-compliance-aids-stability-tool/ (Accessed February 2025)

2. Nottingham University Hospitals NHS Trust MiDatabank Version 3.1. Enquiry number Q104123. Enquiry completed March 2020

3. Albert V, Lanz M, Imanidis G, et al. Stability of medicines after repackaging into multicompartment compliance aids: eight criteria for detection of visual alteration. Drugs Ther Perspect. 2017;33:487-496. Doi: 10.1007/s40267-017-0431-9