



10<sup>th</sup> May 2021

## **IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS**

### **Update in dosing information in the Madopar product information with respect to food**

**PA2307/004/001 - Madopar 200 mg/50 mg hard capsules**  
**PA2307/004/002 - Madopar 50 mg/12.5 mg dispersible tablets**  
**PA2307/004/003 - Madopar 100 mg/25 mg dispersible tablets**

Dear Healthcare Professional,

It was noted that the dosing information (specifically the timing of dosing with respect to food) in the product information for the listed Madopar products was not optimal: it did not make clear that dosing without food is possible, and may be preferable for some patients. This update makes the Madopar dosing information with respect to food more consistent with other levodopa containing medicines and with most clinical guidance.

Roche Products (Ireland) Limited in agreement with the Health Products Regulatory Authority (HPRA) would like to inform you of the following update.

- SmPC Section 4.2 Method of Administration updated the dosing information with respect to food to include the below:
  - Where possible, Madopar should be taken in-between meals, so that the competitive effect of dietary protein on levodopa can be avoided and to facilitate a more rapid onset of action.
  - A delay between a meal and Madopar dosing may be advisable to avoid lower absorption of levodopa by food.
  - Undesirable gastrointestinal effects, which may occur mainly in the early stages of the treatment, can largely be controlled by taking Madopar with a low protein snack or liquid or by increasing the dose slowly.

Consequently, the Patient Information Leaflet has been updated to reflect this information.

Please ensure awareness of the content of this letter within your team.

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

The updated Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) is available on [www.medicines.ie](http://www.medicines.ie).

**Roche Products  
(Ireland) Limited**

3004 Lake Drive, Citywest  
Naas Road, Dublin 24  
Ireland, D24 K661  
(Registered Office)

Tel: 353-1-4690700  
Fax: 353-1-4690790  
353-1-4690791

Registered in Ireland  
No. 214337

*Directors:*

A. Muir (British), E. Hassan (Egyptian), G. Cahill (Irish), B. Kraehenmann (Swiss), S. Davis (British - Company Secretary)



### **Call for reporting**

Healthcare professionals should report any adverse events suspected to be associated with the use of Madopar to: the Drug Surveillance Centre in Roche Products (Ireland) Limited by telephone (01-4690700) or email (Ireland.drug\_surveillance\_centre@roche.com).

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie).

### **Company contact point**

Should you have any questions regarding the use of Madopar (levodopa, benserazide) please feel free to contact Medical Information at Roche Products (Ireland) Limited by telephone (01 4690700) or email (Ireland.druginfo@roche.com).

Yours sincerely,

DocuSigned by:  
  
 Signer Name: James Mawby  
Signing Reason: I approve this document  
Signing Time: 26-Apr-2021 | 4:34:00 PM CEST  
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**Dr. James Mawby**  
**Medical Director**

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(Ireland) Limited**

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