IMPORTANT MEDICINE SAFETY INFORMATION

19 January 2021

Dear Healthcare Professional

Re: DOPAMINERGIC MEDICINES USED IN THE TREATMENT OF PARKINSON'S DISEASE: RISK OF DOPAMINE DYSREGULATION SYNDROME

In collaboration with the Namibia Medicines Regulatory Council (NMRC), Roche Products (Pty) Ltd would like to inform you of the risk of a dopamine dysregulation syndrome (DDS) that may develop in patients with Parkinson's disease treated with dopaminergic medicines.

The Professional Information (PI) and Patient Information Leaflet (PIL) of dopaminergic containing medicines will be updated accordingly.

Summary
DDS is defined as the compulsive misuse of dopaminergic medicinal products and may result in craving for higher doses of dopaminergic medicines used for the treatment of Parkinson's disease, that are in excess of the doses needed to control movement symptoms adequately. In some cases, this may result in severe dyskinesia. DDS has been observed in some patients with Parkinson's disease during treatment with apomorphine, bromocriptine, cabergoline, levodopa/carbidopa, levodopa/benserazide, pramipexole, ropinirole and rotigoline.

Background on the safety concern

This safety concern is based on the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee's (PRAC) recommendation from 2017, regarding the risk of DDS associated with carbidopa/ levodopa. Following PRAC's recommendations, a review on all dopaminergic medicines was conducted and documented evidence that DDS may occur with chronic use of all dopaminergic medicines was found.

Advice to healthcare professionals
Before the start of treatment with dopaminergic medicines for Parkinson's disease, patients and caregivers must be warned about the potential risk of developing DDS.

It is necessary to advise patients, if taking dopaminergic medicinal products to tell their doctor if the family / caregiver notice any addiction like symptoms.

Healthcare professionals are urged to report all suspected adverse drug reactions (ADRs) or product quality issues to:
The Therapeutics Information and Pharmacovigilance Centre
Email: info.TIPC@mhss.gov.na
Fax: 088 660 6781
Tel: 061 203 2406
e-reporting form: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=NA

Roche Products (Pty) Ltd Contact Details

Company	Product Name	Active Ingredient(s)	Registration Number	Contact Details
Roche Products (Pty) Ltd	Madopar 250 mg FCT	Levodopa/ benserazide 200/50	90/5.4.1/001412	**Tel:** +27 11 502 5000 **Fax:** +27 11 268 5748 **Email:** global.irt_sahubtcs@roche.com

References

1. Cartoon J, Ramalingam J. Dopamine dysregulation syndrome in non‐Parkinson's disease patients: a systematic review. Australas Psychiatry. 2019; 27(5): 456‐461.

2. Evans AH,. Lees, JA. Dopamine dysregulation syndrome in Parkinson's disease. Curr Opin Neurol. 2004; 17:393–398.

Yours sincerely,

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