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TO WHOM IT MAY CONCERN

May 2019

Important information for HCPs involved in treating patients with Prasugrel

Dear Healthcare professional,

This educational material was prepared in collaboration with HPRA.

Prasugrel Accord belongs to a group of medicines called anti- platelet agents. Please find enclosed the following educational material containing important safety information. Please make yourself familiar with this information which has implications for patient safety before, during and after Prasugral treatment. Contained in the SmPC is information regarding the increased risk of bleeding (severe haemorrhagic events) in patients with unstable angina pectoris (UA) / myocardial infarction without ST elevation (NSTEMI) when prasugrel is administered prior to diagnostic coronary angiography.

- Severe haemorrhagic events are more frequent with prasugrel in patients ≥ 75 years of age (including fatal events) or those weighing < 60 kg (see annex 6 of the RMP).
- Treatment with prasugrel is generally not recommended for patients of ≥ 75 years of age (see annex 6 of the RMP).
- If, after a careful individual benefit/risk evaluation by the prescribing physician, treatment is deemed necessary in the ≥ 75 years age group then following a loading dose of 60 mg, a reduced maintenance dose of 5mg should be prescribed (see annex 6 of the RMP).
- Patients weighing < 60 kg should have a reduced maintenance dose of 5 mg. The evidence for a 5mg dose is based only on PK/PD analyses and no clinical data currently exist on the safety of this dose in the at-risk sub groups (see annex 6 of the RMP).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse reactions can also be reported to Medical Information at Accord Healthcare Ltd. via E-mail: medinfo@accord-healthcare.com; Tel: +44 (0) 1271 385 257; or by completing the online form at www.accord-healthcare.ie/drug-reaction-report. If you need additional information or you would like to request additional copies of the above mentioned materials please contact Actavis Ireland Ltd, a subsidiary of Accord Healthcare Ltd., Euro House, Euro Business Park, Little Island, Cork, T45 K857, Ireland; E-mail: www.accord-healthcare.ie/medical-information-form; Tel: (0)21 461 9040.

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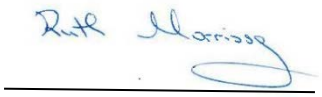
Yours sincerely,



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