Educational Material for healthcare professionals

Key safety information regarding prasugrel use

Prasugrel belongs to pharmacotherapeutic group of Platelet aggregation inhibitors. Prasugrel, co administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndrome (i.e. unstable angina, non-ST segment elevation myocardial infarction [UA/NSTEMI] or ST segment elevation myocardial infarction [STEMI]) undergoing primary or delayed percutaneous coronary intervention (PCI).

There is an increased risk of bleeding associated with prasugrel in patients with anaemia, thrombocytopaenia or a history of pathological intracranial finding and in the following patient groups:

- Patients ≥ 75 years of age or patients weighing < 60 kg, as the risk of severe haemorrhagic events (including fatal events) are more frequent.
- Patients of ≥ 75 years of age - treatment with prasugrel is generally not recommended.
- 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.
- Patients weighing < 60 kg should have a reduced maintenance dose of 5mg.
- In addition, patients with acute coronary syndromes undergoing PCI treated with prasugrel and ASA showed an increased risk of major and minor bleeding according to the TIMI classification system. Therefore, the use of prasugrel in patients at increased risk of bleeding should only be considered when the benefits in terms of prevention of ischaemic events are deemed to outweigh the risk of serious bleedings.

Read the Summary of Product Characteristics for further information.

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
Tel: +353 1 6764971; Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Adverse Events should also be reported to Mylan by +44(0)8001218267 and UKPharmacovigilance@mylan.com.

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