23 August 2024

Somex Pharma

EDUCATIONAL MATERIAL FOR HEALTH CARE PROFESSIONALS

Educational material for all physicians who may be involved in treating patients with prasugrel, specifically to minimise the bleeding risk in patients ≥75 years of age and patients weighing < 60kg.

MAH Licence Number:

PL15764/0121 - Prasugrel 5mg Film-Coated Tablets
PL15764/0122 - Prasugrel 10mg Film-Coated Tablets

Therapeutic indication:

Prasugrel, co-administered with acetylsalicylic acid, 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 or ST segment elevation myocardial infarction) undergoing primary or delayed percutaneous coronary intervention. (For further information please refer to section 5.1 of SmPC)

In patients ≥ 75 years old, use of Prasugrel is not recommended as this population have a greater sensitivity to bleeding (severe, including fatal, haemorrhagic events) and may have a higher exposure to the active metabolite of Prasugrel. Use should only be considered after a careful individualised benefit-risk evaluation by the prescribing physician. Dosing guidelines should be carefully followed.

Additionally, use in patients weighing < 60 kg is cautioned due to an increase in risk of bleeding (severe, including fatal, haemorrhagic events) and an increase in exposure to the active metabolite.

Important safety and dosing information is provided below for the purpose of benefit-risk assessment of use of prasugrel in patients ≥ 75 years old or weighing < 60 kg. This information is part of the Somex Pharma Risk Management Plan.

The suggested dosage for the prevention of atherothrombotic events in patients ≥ 75 years old or in patients weighing < 60 kg with acute coronary syndrome (UA/NSTEMI) or ST segment elevation myocardial infarction (STEMI) who are undergoing primary or delayed percutaneous coronary intervention (PCI) is a single 60 mg loading dose followed by a reduced maintenance dose of 5 mg per day as follows:

Single Loading Dose	Maintenance Dose	Acetylsalicylic acid dose
60mg	5mg*/day	75mg to 325mg/day

*The evidence for a 5mg dose is based on pharmacokinetic/ pharmacodynamic analyses and no clinical data currently exist on the safety of this dose in this at-risk subgroup.

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The information on age ≥ 75 years old or weight < 60 kg and bleeding risks are included in the SmPC in the following sections:

Section 4.2 "Posology and method of administration"

Section 4.4 "Special warnings and precautions for use"

Section 4.8 "Undesirable effects"

Section 5.1 "Pharmacodynamic properties"

Section 5.2 "Pharmacokinetic properties"

A full copy of the Summary of product characteristics for both the strengths (5mg and 10mg) of Prasugrel is available on EMC website (https://www.medicines.org.uk/emc#gref) and Somex Pharma website (https://www.somexpharma.co.uk/).

Reporting of suspected adverse reactions

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via: the Yellow Card website https://yellowcard.mhra.gov.uk/ the free Yellow Card app available from the Apple App Store or Google Play Store some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected adverse drug reactions to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting adverse drug reactions, you can help provide more information on the safety of this medicine."

Adverse Events relating to our products can also be reported direct to our Pharmacovigilance team on 020 8590 9399, or by email to pharmacovigilance@somexpharma.com

Any drug product quality complaints (including suspected defective medicines) relating to our product can be reported directly to our Quality Assurance Team on 020 8590 9399 or by email to qa@somexpharma.com

Company contact point

If you have any questions about this letter or require more information about PRASUGREL please contact our Medical Information by email medinfo@somexpharma.com

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