DORSET MEDICINES ADVISORY GROUP

SHARED CARE GUIDELINES FOR PRESCRIBING PRASUGREL

INDICATION

Prasugrel is a third generation platelet aggregation inhibitor. Its active metabolite irreversibly binds to the P2Y12 class of ADP receptors on platelets. Prasugrel (Efient®) in conjunction with aspirin is indicated for the prevention of atherothrombotic events in 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).

NICE TA317 which replaces TA182 for prasugrel states:
Prasugrel 10 mg in combination with aspirin is recommended as an option within its marketing authorisation, that is, for preventing atherothrombotic events in adults with acute coronary syndrome (unstable angina [UA], non-ST segment elevation myocardial infarction [NSTEMI] or ST segment elevation myocardial infarction [STEMI]) having primary or delayed percutaneous coronary intervention.

Following consideration of the therapy options it has been locally agreed that prasugrel may be considered as a treatment option where patients are unable to take the recommended alternatives.

In patients with acute coronary syndrome (ACS) who are managed with PCI, treatment for up to 12 months is recommended, unless the discontinuation of prasugrel is clinically indicated prior to this.

Prasugrel is administered orally with or without food. An initial loading dose of 60 mg is followed by a dose of 10mg daily for adults with a body weight over 60kg. High risk patients such as those > 75 years, <60kg and those with a previous TIA or stroke should not be prescribed prasugrel. These tablets should not be crushed or broken.

AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of prasugrel can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

REFERRAL AND INITIATION

Shared Care is only appropriate if it provides the optimum solution for the patient. patients will only be referred to the GP once the GP has agreed in each individual case

Specialist Responsibilities	
1	To assess the patient and establish the diagnosis, determine a management strategy and ensure appropriate follow-up in conjunction with the GP.
2	Where appropriate: • to assess suitability of the patient for treatment • to initiate, providing the loading dose and a subsequent supply of at least 28 days treatment; • obtain consent from the patient's GP to continue prescribing once treatment has been stabilised; • monitor the patient and their therapy at appropriate intervals; • ensure therapy is discontinued at the end of 12 months where applicable.
3	Ensure that patients know what to do and who to contact if they experience adverse events or an exacerbation of their condition.
4	To provide the GP with appropriate prescribing information (including length of course) and any additional information requested.
5	To be available for advice if the patient's condition changes.
6	To ensure that procedures are in place for the rapid re-referral of the patient by the GP.
7	To ensure the patient has given informed consent to their treatment.
8	To liaise with the GP on any suggested changes in prescribed therapy.
9	To discontinue treatment if no longer thought to be beneficial.
General Practitioner Responsibilities	
1	Initially, to refer the patient for specialist advice.
2	Where appropriate to continue to prescribe prasugrel and ensure discontinuation where applicable including adding a stop date on the prescription.
4	To deal with general health issues of the patient.
5	To liaise with the consultant regarding any complications of treatment.
Patient's role (or that of carer)	
1	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2	Attend appropriate consultant and GP appointments
3	Share any concerns in relation to treatment with prasugrel
4	Use written and other information on the medication.
5	Seek help urgently if suspect side effects, or otherwise unwell.

Dosage and Administration
Initial loading dose:
Adults under 75 years: 60mg - Patients should also take aspirin concomitantly.

Maintenance dose:
Adults under 75 years and >60kg: 10mg once daily No dose adjustment is necessary for patients with renal impairment, including patients with end-stage renal disease or subjects with mild to moderate hepatic impairment

Contraindications
Prasugrel is contraindicated:

- in patients with a known hypersensitivity to the drug or any of its excipients
- in patients with active pathological bleeding
- in patients with a history of stroke or transient ischaemic attack
- severe hepatic impairment

Special Warnings
Prasugrel should be used with caution in patients with a propensity to bleed, anaemia; thrombocytopenia; a history of pathological intracranial findings, patients weighing less than 60kg and patients over 75 years of age. If used in these groups after a careful assessment of the risks and benefits a reduced maintenance dose of 5mg should be considered. Caution to be used when considering concomitant administration of medicinal products that may increase the risk of bleeding, including oral anticoagulants, clopidogrel, non-steroidal anti-inflammatory drugs (NSAIDs), and fibrinolytics

Side Effects
Common side effects include: bleeding, anaemia, haematoma, epistaxis, gastrointestinal haemorrhage, rash, ecchymosis, haematuria, vessel puncture site haematoma, puncture site haemorrhage, contusion**.**
Uncommon side effects include: Hypersensitivity including angioedema, eye haemorrhage, haemoptysis, retroperitoneal haemorrhage, rectal haemorrhage, haematochezia , gingival bleeding, post-procedural haemorrhage.

Drug Interactions Because of the potential for increased risk of bleeding, concomitant administration with NSAIDs or COX-2 inhibitors is not advised. This product should be used with caution in patients taking warfarin. Prasugrel is a weak inhibitor of CYP2B6 and can thus affect metabolism of drugs such as bupropion, cyclophosphamide and efavirenz. At current prices 28 day's supply (BNF March 2013) costs: 28 x 5mg prasugrel tablets = £47.56 28 x 10mg prasugrel tablets = £47.56

The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.

References

1. Efient® (Prasugrel) – Ely Lilly and Company Daiichi Sankyo UK Limited Summary of Product Characteristics. Available at http://www.medicines.org.uk/emc/medicine/21504 Accessed August 2014.
2. TRITON-TIMI 38 double blind, randomized trial.
3. British National Formulary (online) London: BMJ Group and Pharmaceutical Press. http://www.medicinescomplete.com Accessed on 29/8/14
4. National Institute for Clinical and Care Excellence Technology Appriasal Guidance 317 available at http://www.nice.org.uk/guidance/TA317/chapter/1-Guidance Accessed August 2014

Developed By	**Cardiology Sub-group**	**July 2009**
Updated by	**Cardiology Sub-group**	**March 2013**
	Cardiology subgroup	**August 2014**
Approved By	**Bournemouth, Dorset and Poole Health Technologies Forum**	**April 2013**
	Dorset Medicines Advisory Group	**Sept 2014**