PostScRxipt – PrimaRxy Care

NHS Greater Glasgow and Clyde

February 2010

CLOPIDOGREL IN MONITORED DOSAGE SYSTEMS: Generic copies of Plavix® (clopidogrel hydrogen sulphate) have been available since August 2009. Generics are either the hydrochloride or besilate salts.

All available generic clopidogrel preparations are licensed for prevention of atherothrombotic events in adults and some also have a license for acute coronary syndrome (ACS). However, because the combination of aspirin with Plavix® for the treatment of ACS has patent protection, generic companies cannot market generic clopidogrel in combination with aspirin for the ACS indication.

In support of the use of generic clopidogrel the Area Drug and Therapeutics Committee have stated that: "*generic versions of a medicine may not have the exact same indications listed on the market authorisation as the original branded medicine, but as bioequivalence to the original branded medicine must have been demonstrated as part of the generic market authorisation process, ADTC considers that any additional risks of prescribing and dispensing the medicine generically are negligible*."
www.ggcformulary.scot.nhs.uk/Postscript/PS54.pdf

There have been reports of physical changes occurring to some generic versions when removed from original packaging and dispensed into monitored dosage systems (MDS). There have been no similar reports for Plavix®. Companies marketing generic clopidogrel hydrochloride warn that their preparations need to be protected from moisture and light (and some SPCs advise that the product should be stored in the original container). Clopidogrel besilate versions and the originator Plavix® do not have these warnings.

In summary:

1. The **ADTC endorse the prescribing of generic clopidogrel** despite differences in the licensed indication between Plavix® and some generic versions (not all).
2. the hydrochloride salt of clopidogrel is known to be hygroscopic and the SPCs have stated storage requirements regarding light and moisture (and some even about original container)
3. the besilate salts (eg Grepid®(Beacon Pharmaceuticals), Dr Reddy's clopidogrel, Actavis UK, Dexcel Pharma Ltd) do not have specific storage requirements detailed in their SPCs but like Sanofi-Aventis they do not have any specific data on file regarding dispensing into MDS.
4. Plavix® has been dispensed into MDS in the past despite there being no data to support this (there have been no reports of problems).

SIBUTRAMINE WITHDRAWAL: The European Medicines Agency (EMA) has completed a review of the obesity treatment Reductil® (sibutramine) following new safety information from the Sibutramine Cardiovascular Outcomes Study. The EMA has concluded that the cardiovascular risks outweigh the benefits. The MHRA have advised that sibutramine should no longer be prescribed and pharmacists should advise patients presenting with prescriptions for sibutramine to make an appointment with their GP when convenient.

PRESCRIPTION PAD REQUIREMENTS: As part of a workstream to investigate the reasons for the £1.8million of unallocated prescriptions in the last year; it has been highlighted that there are significant numbers of prescriptions issued on the wrong form type for the prescriber type. All prescribers are reminded that they may only legally prescribe using their own prescription forms. For instance only GP10 for medical practitioners, GP10N for nurses, GP10P for pharmacist prescribers and GP10NMP for allied health profession prescribers. The prescription should also bear the prescriber's correct cipher code and professional registration number. Prescriptions which are written or printed on the wrong form or which do not bear the correct prescriber details cannot be dispensed by a community pharmacist. The acute medication service which involves barcoded prescriptions are only in use for medical practitioner prescriptions (GP10) at present.

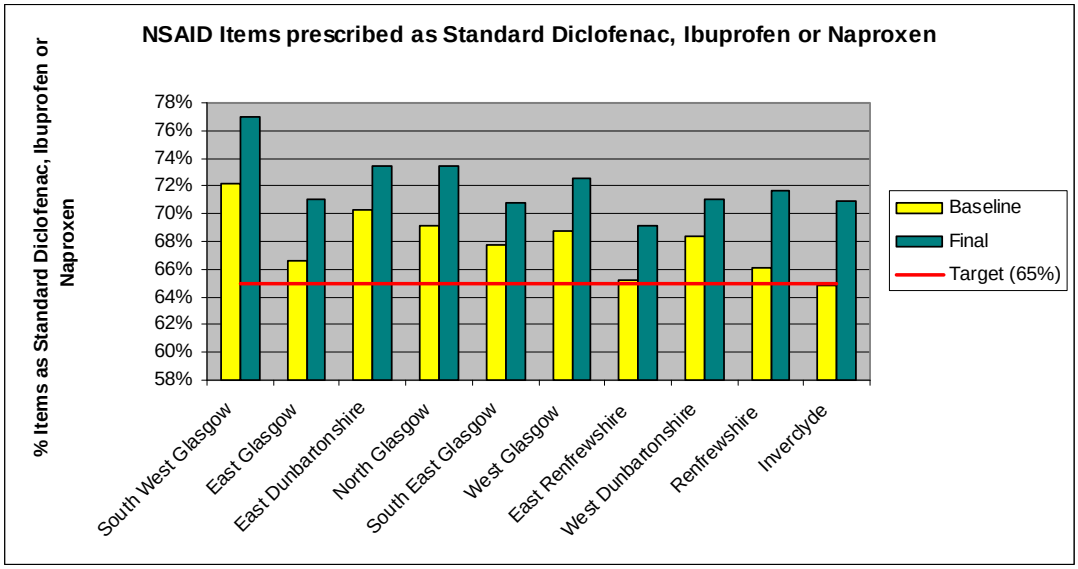
INDICATOR FEEDBACK FROM 2008/09

NSAIDS: Diclofenac, ibuprofen and naproxen are included in the preferred list of the formulary.

One of the Rational Prescribing scheme (PRS) indicators was:

Standard diclofenac sodium, ibuprofen & naproxen should account for at least 65% all NSAIDS including Cox-2s

The following chart illustrates the change in prescribing rate between the RPS baseline (October to December 2007) and the final measurement using data from October to December 2008:



This indicator saved NHSGG&C approximately **£283K** during 2008/09

CIPRAMIL® DROPS: Cipramil drops are supplied in a bottle with a dropper for ease of administration. Citalopram oral drops have approximately 25% increased bioavailability compared to tablets. On the rare occasion when switching between citalopram tablets and citalopram drops to ensure the same therapeutic effect is achieved this difference should be taken into account.

The tablet corresponds to the number of drops as follows:

Tablets	Dose Equivalent	Drops
10 mg	8 mg	(4 drops)
20 mg	16 mg	(8 drops)
30 mg	24 mg	(12 drops)
40 mg	32 mg	(16 drops)
60 mg	48 mg	(24 drops)

The dose for citalopram oral drops should be stated in drops, not in terms of mls to avoid confusion for patients (1ml = 20 drops), and also for ease of administration. The bottle is fitted with a dropper to facilitate this and to ensure accurate dosing. Also the oral drops should be mixed with water, orange juice or apple juice before taking. The resulting solution must be drunk by the patient immediately.

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