NORTHERN IRELAND MEDICINES MANAGEMENT NEWSLETTER

Health and Social Care Board

August 2012

Volume 3, Issue 3

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PRODUCT FOCUS: MEZOLAR MATRIX® PATCHES

Mezolar Matrix® is the preferred branded fentanyl patch for use in Northern Ireland; all hospitals are now stocking this brand. Use of the same product across primary and secondary care will result in patient benefits in terms of consistency of supply, alongside significant efficiencies.

A standard operating procedure is available on the Primary Care internet to assist practices in switching patients across to Mezolar®.
The site also contains information on the other preferred Product Standardisation choices:

http://www.hscboard.hscni.net/medicinesmanagement/Correspondence/070%20February%202012%20-%20Letter%20-%20Update%20Product%20Stand%20%20Amended%20-%20PDF%20407KB.pdf

Contains Soy-bean oil

Mezolar Matrix® contains soy-bean oil in the adhesive layer and is therefore contraindicated in patients with peanut or soya allergy.
This is clearly stated in both the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SPC), as per EMEA requirements.
There are significant numbers of medicines available (both over-the-counter and on prescription) that are contraindicated in patients with a peanut allergy. As with all medicinal products that are contraindicated in specific patient groups, alternative products may be prescribed to meet individual patient need.

PATIENT GROUP DIRECTIONS (PGDs) IN PRIMARY CARE

A Patient Group Direction (PGD) is a written instruction for the supply and/or administration of a named licensed medicine for a defined clinical condition. PGDs are used to allow non-prescribing healthcare professionals to take a decision to supply and/or administer an identified Prescription Only Medicine to a patient with an identified clinical condition, without the patient needing to see a prescriber.
PGDs have been developed regionally for a number of medications of which childhood vaccines and annual flu vaccine are of most relevance to general practice. The PGDs are created and reviewed jointly by the HSCB and Public Health Agency (PHA) who ensure the content is correct and proper process has been followed in their development. It is important that GPs and nursing staff are aware of their responsibilities with regard to PGDs in use in their practice.

For **practice employed nurses,** the authorising GP needs to sign the PGD naming the specific healthcare professionals who the PGD will apply to. It is the GP's responsibility to ensure that only fully competent, qualified and trained healthcare professionals operate under the PGD. In addition, the Nursing and Midwifery Council (NMC) recommend that healthcare professionals acting under the PGD must also sign the PGD – this will also act as the list naming the staff it applies to.

Trust employed staff are authorised by their Trust Governance Lead to use PGDs. The Trust is responsible for ensuring that staff meet the requirements of the PGDs, and use them accordingly.
GPs do not need to sign PGDs on behalf of Trust employed staff, even if treating patients from their practice.

PGDs are reviewed at least every two years. Even where review of a PGD results in minor or no changes, it still must be reauthorised by those using it. For example, the PGD for flu vaccine is generally reviewed annually, so when this is issued each year it must be re-signed by the authorising GP in the practice along with the staff operating under it.

Each practice should have a system in place to retain the signed copies of the PGD and lists of authorised practitioners. The same rules apply to PGD records as to all other patient records. For adults, all PGD documentation must be kept for eight years and for children until the child is 25 years old, or for eight years after a child's death.

PGDs can be found on the HSCB Primary Care intranet http://primarycare.hscni.net/PharmMM_Resources_Clinical%20Resources.htm#PGDs
Further information on PGDs can be found in the NPC document 'Patient Group Directions' (2009). The GPC has also issued a guidance document specifically aimed at GPs entitled 'Patient Group Directions and Patient Specific Directions in general practice' (2010)

Action:

Healthcare staff should familiarise themselves with the guidance on PGDs and ensure that they are compliant with this.

QUETIAPINE EXTENDED-RELEASE – ANY ADVANTAGE?

No evidence that extended-release quetiapine tablets improve efficacy, tolerability or adherence

The patent protection for Seroquel® expired in March 2012. Astra Zenecca lost the patent for both immediate release (IR) and extended-release (XR) quetiapine in the UK at that time. Generic IR and XR quetiapine preparations are now available. A switch to quetiapine extended-release (XR) tablets is currently being promoted to GPs and secondary care psychiatrists.

Both preparations are licensed for the treatment of schizophrenia and bipolar disorder, including manic episodes or major depressive episodes; the XR formulation is also licensed as an add-on treatment of major depressive episodes in patients with major depressive disorder who have had sub-optimal response to antidepressant monotherapy.

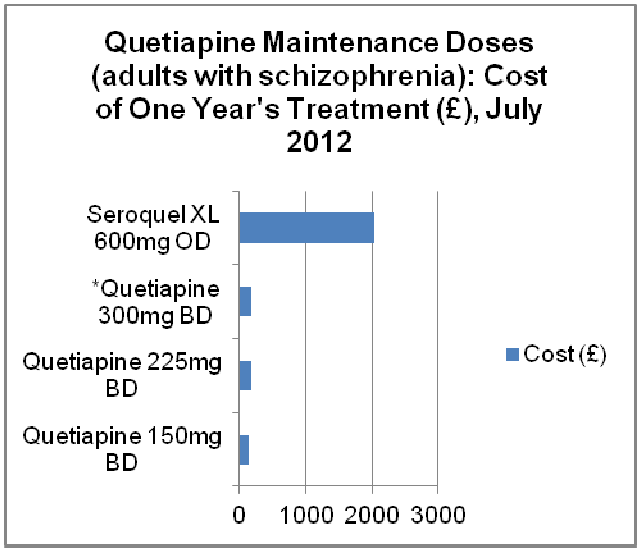
What evidence is available to compare the two formulations?

Research findings indicate that modifying the formulation:

- does not change the overall absorption or elimination of quetiapine (**unless taken with food** – see later)
- has no difference in efficacy
- has no difference in adverse effects or tolerability between the two formulations

A relationship between dosing frequency and adherence has not yet been assessed.

Cost of quetiapine



*usual dose range of quetiapine IR for schizophrenia is 300-450mg daily

Once-daily dosing with quetiapine XR tablets is equivalent to twice-daily dosing with quetiapine IR tablets, e.g. Seroquel® XR 600 mg once daily is equivalent to quetiapine IR 300 mg twice daily

Practice points to note about the extended release formulation

- The XR tablets come in different strengths to those of the IR tablets.
- Most of the XR tablets have different shapes and markings to the IR tablets. Note however that the quetiapine XR 400 mg tablet has a similar appearance to the quetiapine IR 300 mg tablet.
- Different dosing schedules exist for each indication. It must therefore be ensured that patients receive clear information on the appropriate dosage for their condition.
- XR tablets are taken once daily. People may prefer evening dosing to minimise any daytime sleepiness.
- XR tablets should not be chewed, crushed or split.

XR tablets should ***not*** be taken with food; they should be taken at least one hour before a meal. In one study using XR tablets, a high-fat meal increased the peak blood levels of quetiapine and overall absorption. Raised blood levels of quetiapine may increase the risk of adverse effects.

Action for prescribers

⇒ Do not switch from IR preparations to XR preparations unless there is a clear patient benefit anticipated.

⇒ Ensure that patients receive clear information so that confusion between the two formulations is avoided.

⇒ Further information on prescribing antipsychotics is available on the HSCB Internet.

This newsletter has been produced for GPs and pharmacists by the Regional Pharmacy and Medicines Management Team. If you have any queries or require further information on the contents of this newsletter, please contact one of the Medicines Management Pharmacists in your local HSCB office.

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Did you see…?

MHRA ISSUES FURTHER GUIDANCE ON DABIGATRAN AND MANAGING RISK OF HAEMORRHAGE

The MHRA has issued further information and clearer guidance on the risk of bleeding with dabigatran.

Healthcare professionals should note the following warnings with dabigatran:

- Contraindicated in conditions that increase the risk of bleeding, e.g. current or recent GI ulceration
- Contraindicated in combination with dronedarone
- Renal function monitoring required –
  - assess in all patients before starting treatment
  - review annually in patients over 75yrs of age OR those with suspected decline in renal function
  - dabigatran is contraindicated in patients with severe renal impairment (<30mL/min)
- Caution with anti-platelets

The MHRA has issued further advice on:

- switching anticoagulant treatment to and from dabigatran
- how to manage haemorrhagic complications.

Full details can be found on the MHRA website (www.mhra.gov.uk). The SPC for Pradaxa® (dabigatran) is to be updated accordingly.