PostScRxipt – PrimaRxy Care

November 2008

ETORICOXIB NEW ADVICE:

The European Medicines Agency has recently undertaken a review of the benefits and risks of etoricoxib in the treatment of rheumatoid arthritis and ankylosing spondylitis. It reported that a substantial number of patients with uncontrolled blood pressure were initiated on etoricoxib despite the earlier contraindication in these patients.

Prescribers are reminded that:

- **Uncontrolled hypertension is a contra-indication to etoricoxib use**
- BP should be monitored within two weeks of initiating etoricoxib in all patients and monitored periodically thereafter.
- Etoricoxib is a black triangle drug, therefore all adverse drug reactions should be reported to the CSM using the yellow card scheme.
- Etoricoxib is included in the NHSGG&C Formulary for acute gout only.

RIMONABANT WITHDRAWAL:

The European Marketing Authorisation for rimonabant (Acomplia®) has been suspended because the benefits do not outweigh the risks. The most recent assessment showed that there was approximately a doubling of the risk of psychiatric disorders in obese or overweight patients taking rimonabant compared to those taking a placebo. At the time of approval, psychiatric side-effects (particularly depression) were identified as the most important safety issue and relevant warnings were included in the product information since its first authorisation. Patients who may be at highest risk of psychiatric reactions cannot be identified reliably. The measures and clinical advice implemented to date to try to reduce the frequency of psychiatric reactions with rimonabant have not adequately controlled this risk.

NHS Greater Glasgow and Clyde

Patients currently taking rimonabant should consult their doctor or pharmacist when convenient to discuss their treatment. Patients who wish to stop taking rimonabant can do so at any time.

Prescribers should not issue any prescriptions for rimonabant and should review the treatment of patients currently taking the medicine. For further information please go to the EMEA website www.emea.europa.eu

Orlistat and sibutramine, two other treatment options for obesity, are included in the NHSGG&C Formulary. Both are restricted to use for patients with BMI >30 with relevant co-morbidities and BMI >35 without co-morbidities. Other conditions for prescribing should be in accordance with NICE CG43. Either drug should be prescribed only through the Glasgow and Clyde Weight Management Service.

MIDAZOLAM INJECTION FOR PALLIATIVE CARE PATIENTS:

We have had notification that a number of prescribing errors have been made in relation to the choice of midazolam injection for palliative care. The usual strength for this indication is **midazolam 5mg/ml 2ml ampoule** (ie midazolam 10mg/2ml) and this is the product stocked by the palliative care network pharmacies. It appears to be relatively common for the wrong preparation to be chosen from the clinical software. As midazolam is a controlled drug, the pharmacist cannot make alterations to the prescription and substitute the correct item but must return it for amendment by the prescriber. This can result in delays in supply which are distressing for the patient and their carers.

Please take care when selecting the product to ensure the correct strength and ampoule volume is prescribed.

GUIDANCE ON MIXING MEDICINES

There have been recent statements from the Nursing Midwifery Council (NMC) and the Chartered Society of Physiotherapy regarding the prescribing of drugs to be mixed prior to administration. For physiotherapists, drugs that have been mixed are steroids and lidocaine, for nursing in palliative care this has been opioids and other drugs for symptom control. The MHRA are aware of the issues and has been meeting with palliative care professionals, nursing and pharmacy organisations to identify the options and way forward. The MHRA understands there is a body of evidence to support the mixing of certain medicines in a syringe pump that is safe and effective. There is no clear date on when this current situation will change.

LEGAL FRAMEWORK: The legal advice obtained from the MHRA is that when two medicinal products are mixed and one cannot be described as a vehicle for the other (eg diluting agents such as saline), this is termed 'manufacture' under the Medicines Act and results in an **unlicensed product**.

PALLIATIVE CARE GUIDELINES: There are local guidelines for management of symptoms in palliative care patients within NHSGG&C. They include information from stability studies on the compatibility of a limited range of drugs which may be mixed together for subcutaneous infusion. Staff should take account of the guidelines for the use of subcutaneous medicines in palliative care. Palliative care pharmacists can provide clinical and pharmaceutical advice on the recommended drugs for use in palliative care. To ensure continued care for patients the options for prescribing which will ensure prescribers are acting within the legal framework are:

SUPPLEMENTARY PRESCRIBING USING CLINICAL MANAGEMENT PLANS (CMPs): Independent non-medical prescribers (NMPs) are also supplementary prescribers and as such can prescribe unlicensed medicines within a Clinical Management Plan (CMP) with the patient knowledge and consent.

Independent NMPs are not authorised to prescribe unlicensed medicines. While the individual medicines are licensed, mixing produces an unlicensed product which therefore cannot be prescribed by independent NMPs at present.

Planning is an important part of palliative care and can be used to gain agreement for the CMP in advance of its need. This enables the patient to be involved in the decisions about their medicines and pain relief which may not be possible at the later stages.

Supplementary prescribing can be used when the patient requires the use of a syringe pump, including mixtures of two or more drugs. The CMP can make reference to the local and national palliative care guidelines for the management of pain and other symptoms.

PRESCRIBING BY MEDICAL PRESCRIBERS: Doctors and dentists are covered by the exemptions to the Medicines Act 1968 and so are able to prescribe unlicensed medicines for use for named individual patients. Doctors can continue to prescribe mixtures of drugs for subcutaneous infusion for their patients and nurses can administer these medicines according to the prescription or directions on the patient held record of medicines.

RECENT ADVICE: The MHRA is advising that in the current circumstances for palliative care they would not proceed with enforcement action where the NMP is engaged in the long standing accepted practice of prescribing and administering a mixture of licensed medicines via a syringe pump unless it would be in the public interest to do so. This also applies to those mixing and administering medicines in accordance with the directions of a prescriber.

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