Health and Social Care Board

Medicines Safety Matters

Newsletter for Prescribers & Community Pharmacists

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Inside this issue:

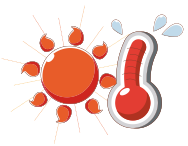
Fentanyl Patches–Caution to patients to avoid heat sources

A Coroner's report on a patient death in England in 2011 told of a 67 year old woman who died after taking a hot bath while wearing two fentanyl transdermal patches. The woman had applied a new patch but not taken the old one off.

Further to this incident, The Royal Pharmaceutical Society issued a reminder in December 2011 about the need to advise patients about avoiding heat sources e.g. heat lamps, prolonged hot baths, which can increase absorption while using fentanyl patches. The U.S. Food and Drug Administration (FDA) and the MHRA in the U.K. have issued previous warnings about the safe use of fentanyl patches following reports of deaths.

Examples of heat sources to avoid:

Hot water bottles
Heat or tanning lamps
Electric blankets
Hot spa baths
Prolonged hot baths
Heating pads



Advise patients to read the patient information leaflet carefully

Directions for safe use:

- Follow the prescribed dose and correct frequency of administration
- Ensure old patches are removed before applying a new one
- Do not cut patches
- Avoid touching the adhesive side and wash hands after application
- Follow instructions for safe storage and disposal.

Signs of fentanyl overdose:

Ensure that patients and carers are aware of the signs of fentanyl overdose i.e., trouble breathing or shallow breathing; tiredness; extreme sleepiness or sedation; inability to think, walk or talk normally; and feeling faint, dizzy or confused. Patients or caregivers should be advised to seek medical attention immediately if overdose is suspected.
Patches should be removed immediately and the patient monitored for up to 24 hours after patch removal.

Fentanyl is a potent opioid analgesic; a 25 microgram per hour patch is equivalent to up to 90 milligrams of oral morphine over one day.

See primary care intranet for an opioid equivalents chart:
http://primarycare.hscni.net/PharmMM_Resources_Clinical%20Resources.htm#Pain

Further reports of levomepromazine mix-ups

Prescribers should remain vigilant for possible mix-ups when prescribing levomepromazine for control of nausea and vomiting in palliative care.
Two strengths are available under different brand names; **25mg (Nozinan®) and 6mg (Levinan® unlicensed)**.
Prescribers should be aware that there is potential for a 4-times overdose if the wrong product is selected and the additional sedative effects caused can be significant, especially if used in combination with other drugs known to have CNS side effects.
See Medicines Safety Matters vol 1 issue 2 Sept 11 for more details.

Advice for prescribers:

Be aware of the two strengths of levomepromazine

Check referral letters carefully to establish which strength is required

Prescribe levomepromazine by generic name to ensure both brands & strengths appear in your pick list.

Signed Prescriptions — Missing in Transit

A number of incidents have been reported recently where signed prescriptions have gone missing during transit **from the GP practice to the community pharmacy**. Prescriptions contain personal and sensitive information and are covered by the requirements of the Data Protection Act.

1. Collection from the Practice by Pharmacies:
Ideally prescriptions should be collected by a member of pharmacy staff. Practice staff should be satisfied as to the identity of the person collecting the prescriptions before allowing prescriptions to be removed. If this is not a member of pharmacy staff e.g. delivery van driver, the use of tamper-proof envelopes should be considered. **Practices should keep a record of prescriptions collected by each pharmacy including patient details and the number of prescriptions.**
Community pharmacies should have procedures in place to avoid duplicate prescription requests.

2. Posting:
Ideally prescriptions should not be posted. If posting is necessary, use of standard post should be minimised; this includes free-post envelopes. Alternatives should be explored e.g. collection by the patient's representative. If no other method of prescription transfer is available, secure postal service is preferred. Records should be kept of all prescriptions posted.
Where it is decided that a significant level of risk remains with a method of prescription transfer e.g. posting, the practice should obtain informed consent from each patient prior to transferring prescriptions by this method.

Advice for GP Practices and Community Pharmacies:

Arrangements for transferring signed prescriptions should be agreed between the community pharmacy and GP practice and assessed to minimise the risk of prescriptions going missing in transit.
If it is necessary to make changes to current arrangements for transferring prescriptions, patients should be adequately informed.

GP practices should refer to the HSCB Guidance on Prescription Security for further details.http://primarycare.hscni.net/PharmMM_Resources_Non%20Clinical%20Resources.htm

HSCB has also produced a guide for community pharmacists on patient/client data and The Data Protection Act

http://www.hscboard.hscni.net/medicinesmanagement/Medicines%20Governance/index.html#P-1_0

Re-dispensing hospital drugs is not recommended

We have received a number of queries involving the re-dispensing of the red list antipsychotic medication clozapine, which was supplied by the hospital pharmacy and taken to the community pharmacy where it was re-dispensed into a monitored dosage system.

Advice for pharmacists:

- It is not recommended that a pharmacist re-dispenses medicines which were originally supplied by another pharmacy, into compliance aids. A pharmacist who fills and checks a compliance aid with medicines that had originally been dispensed elsewhere would then become liable for the supply of the medication. In this situation, it would be difficult to be certain of the quality and safety of the medicines, and storage conditions prior to re-dispensing, particularly if the medications had left the pharmacy supply chain and been passed into the public domain.

- The pharmacist re-dispensing will not have sight of the doctor's ***original*** prescription and would therefore be dispensing against the labels produced by another pharmacy. The pharmacist would be reliant on the accuracy of the original pharmacy's dispensing, and labelling processes.

Advice for prescribers:

- GP practices should not issue prescriptions for medication that has already been supplied by another source in order to facilitate re-dispensing. Prescribers who issue such prescriptions would accept full responsibility for the authorization to supply.

Compliance issues relating to medication supplied by another source e.g. red list medication, should be discussed on an individual basis with the patient's GP and, where applicable, the hospital making the supply.

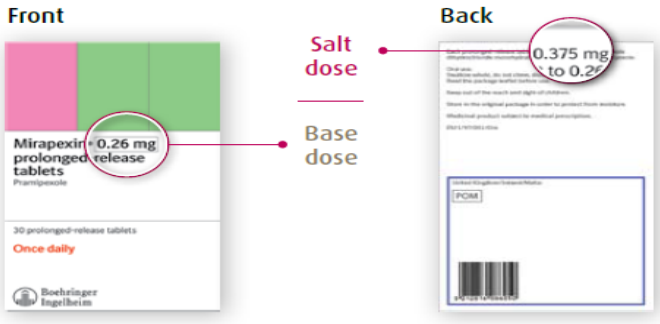
Caution when prescribing & dispensing pramipexole (Mirapexin®)

It can be very confusing when drug manufacturers express the strength of their medication in two different forms. This is the case with pramipexole (Mirapexin®) which is licensed to treat Parkinson's disease and moderate to severe restless leg syndrome. The strength of pramipexole can be expressed as either:

- Base = pramipexole or
- Salt = pramipexole dihydrochloride monohydrate

Why is the strength expressed in two different ways?
In 1998 when Mirapexin® was first licensed, the European Licensing Authority had just changed its policy from licensing a product expressed as salt to licensing a product expressed as base. However the drug company's published studies and promotional material had already expressed the strength in terms of the salt.

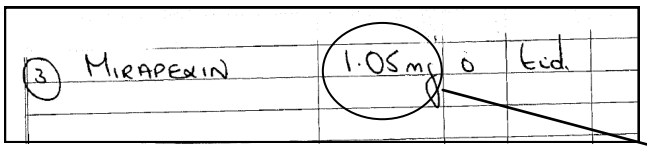
- BNF doses and strengths are stated in terms of the BASE.
- GP clinical systems and prescriptions may present the strength as either base, salt or both.
- Tablet strengths or doses may be stated in milligrams OR micrograms



We covered this issue in our January community pharmacy newsletter based on reports received from pharmacists around the risks when selecting and dispensing Mirapexin® preparations.

GP practices have also reported:

- Confusion when selecting Mirapexin® from the clinical system drug list
- Confusion between once daily prolonged release and three times daily immediate release preparations
- Errors in hospital outpatient letters (see below)



1.05mg is a prolonged release strength for once daily dosing which has been prescribed TID

Dose equivalents for the base and the salt

Base	Salt
Pramipexole (Mirapexin®) ***Three times daily dose for Parkinson's disease*** ***Once daily dose for restless legs***	
88 micrograms base	125 micrograms salt
180 micrograms base	250 micrograms salt
350 micrograms base	500 micrograms salt
700 micrograms base	1mg salt
Pramipexole (Mirapexin®) prolonged release ***Once daily dose for Parkinson's disease***	
260 micrograms base	375 micrograms salt
520 micrograms base	750 micrograms salt
1.05 mg base	1.5 mg salt
1.57 mg base	2.25 mg salt
2.1 mg base	3 mg salt
2.62 mg base	3.75mg salt
3.15 mg base	4.5 mg salt

Advice to prescribers:

Be aware that:

- The strength can be expressed as the salt or the base. In most cases, both will be stated when a prescription is printed
- The BNF recommends that prescribed dose is expressed as the **BASE**
- The strength/dose can be expressed in either milligrams or micrograms
- Standard release and prolonged release Mirapexin® have different strengths
- Standard release Mirapexin® is a TID dose for Parkinson's disease and once daily in the evening for restless legs syndrome
- Prolonged release Mirapexin® is a once daily dose for Parkinson's disease

New warnings about drugs that prolong QT interval: citalopram, escitalopram & domperidone

In December 2011, the MHRA reported on new data concerning the risk of QT interval prolongation with **citalopram and escitalopram**. The potential for these medicines to cause QT interval prolongation has been known for some time, however new data has further defined the risk and clarified that the effect of citalopram and escitalopram is dose-dependent.

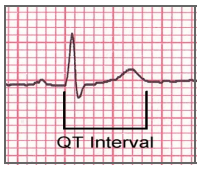
- New restrictions on maximum daily dose

	Adults	Adults>65 years	Adults with hepatic impairment
Citalopram	40mg*	20mg*	20mg*
Escitalopram	20mg	10mg*	10mg

*New (restricted) maximum daily dose

For further information on drugs which prolong QT interval or induce Torsades de Pointes (TdP) see:

www.qtdrugs.org



- Co-administration of citalopram or escitalopram with medicines that prolong the QT interval is contraindicated (see MHRA link for details).
- Citalopram and escitalopram are contraindicated in patients with congenital long QT syndrome or known pre-existing QT interval prolongation.
- Further information is available at:
  http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON137769
- CPD: A learning module on SSRIs approved by the Royal Colleges of Physicians of the UK is available on the MHRA website. The module identifies the most important hazards of SSRIs and provides advice on how to minimise and manage risks.
  http://www.mhra.gov.uk/ConferencesLearningCentre/index.htm

In December 2011, health professionals also received a letter from the manufacturers of **Motilium® (domperidone)** to advise that studies had shown an increased risk of serious ventricular arrhythmias or sudden death. The letter highlighted:

- Risks may be higher in patients over 60 years old and with doses higher than 30mg daily
- Use lowest effective dose
- Avoid co-administration with medicines known to prolong the QT interval
- Domperidone should not be sold as a pharmacy medicine to patients with underlying cardiac disease.

Summary of recent safety advice from MHRA

Drug Safety Update

http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/index.htm

Dec 11	Citalopram Escitalopram	Cipramil® Cipralex®	QT interval prolongation: new max daily dose, contra-indications & warnings
	Dabigatran	Pradaxa®	Risk of serious haemorrhage, need for renal function tests
Jan 12	Atomoxetine	Stratterra®	Increases in blood pressure & heart rate: new contra-indications, warnings & advice for monitoring
	Statins		Risk of hyperglycaemia & diabetes
	Chlorhexidine		Reminder about potential hypersensitivity
Feb 12	Fingolimod	Gilenya®	Transient bradycardias and heart block after first dose—strengthened cardiovascular monitoring
	Blue Dyes	Patent Blue	Risk of serious allergic reactions