Medicines Safety Newsletter

Issue 4 – January 2019

Welcome & Happy New Year!

Before we welcome you to our fourth edition of the Community Pharmacy West Yorkshire Patient Safety Newsletter, may we take this opportunity to wish all our contractors and pharmacy teams a very Happy New Year!

The aim of our Medicines Safety Newsletter is to promote and support safer practice by highlighting to pharmacy teams, medication incidents that have occurred both locally and nationally and sharing the lessons that have been learnt to help prevent these from happening again.

Establishing a safety culture is essential to help protect our patients from harm. All humans are fallible and even the most capable pharmacist, technician or pharmacy team member can make a potentially harmful mistake. Having robust systems in place to both detect errors quickly and prevent them from occurring again is key to a safer working environment.

We hope that you find this newsletter both engaging and informative and encourage you to continue to feed in by letting us know about any significant medicines related incidents that have occurred in your workplace. Please feel free to contact us at Community Pharmacy West Yorkshire (see contact details at the end) if you have any comments or would like us to help you in any way.

Share and Learn

You will already be reporting patient safety incidents nationally, (to the NRLS), and/or via your local reporting system. **Please continue to follow your company's SOP for incident reporting,** however, it would be fantastic if you could also help us to support all our West Yorkshire pharmacy teams by "sharing the learning".

If you have come across or been involved in a dispensing OR prescribing error (or other medicines related incident) it is likely that this may not be a "one off". The chances are that this may have already happened at the pharmacy over the road and may yet happen at the pharmacy in the next town. By reporting incidents and sharing the learning you can prevent this from happening and potentially save a patient from harm. If you are participating in the Quality Payments Scheme you could also use this to demonstrate that you have shared your learning locally as evidence towards the Written Patient Safety Report Quality Criterion.

Report it – for everyone's sake!

If you wish to share any medicines safety incidents, (and your learning), with other West Yorkshire pharmacies via this newsletter please complete the Report, Learn, Share, Act, Review template (click here) and return to info@cpwy.org.

All reports will be treated completely anonymously and no details of who submitted the report will be shared outside of the Community Pharmacy West Yorkshire team. Please remember to NOT send any patient identifiable details.

DOES YOUR PATIENT HAVE A PEANUT ALLERGY?

It is important that the potential for allergic reactions to occur is considered when dispensing or giving out medicines to patients with a known peanut allergy. Peanut oil (labelled as arachis oil) is present in some medicines and these products should be avoided in patients with a peanut allergy. Examples include:

- Naseptin nasal cream
- Cerumol ear drops
- Zinc and castor oil ointment/cream
- Dermovate-NN cream
- Colpermin IBS Relief capsules
- Abidec multivitamin drops

Some **generic salmeterol MDI inhalers** are also contraindicated in patients with a peanut or soya allergy (contain soya lecithin).

This is not intended as an exhaustive list and it should be noted that unlicensed products, food supplements, or imported products may also contain arachis oil and thus should also be avoided in patients with peanut allergy. As there is also a possible relationship between allergy to peanut and allergy to soya most manufacturers advise that patients with a soya allergy should also avoid products containing arachis oil (see here).

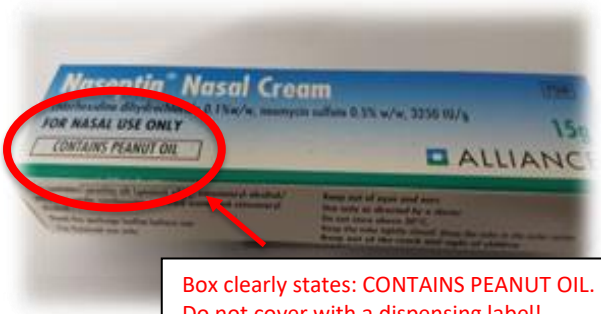
So, what about medicines containing soya? As peanut and soya belong to the same plant family (legumes), concern has been raised that patients allergic to peanuts might also be allergic to soya. There is however no consistent published advice on the risk of cross-sensitivity, and further studies are required to quantify the risk (see here for further information).

Current European guidelines recommend that where products contain soya oil (and hydrogenated soya oil), the package leaflet should warn patients who are allergic to soya or peanuts not to use the product, and a contra-indication should be included in the Summary of Product Characteristics (SPC). Whilst certain medicines containing soya are specifically contra-indicated in individuals hypersensitive to soya or peanuts, others are not.

Individual SPCs should always be checked before dispensing (selling) a product to a patient with a known allergy.

KEY MESSAGES FOR PHARMACY STAFF:

- Patients with a known peanut allergy or a family history of peanut allergy should **NOT** receive medicines containing peanut oil (sometimes labelled as arachis oil).
- **ALWAYS** check the patient information leaflet/SPC if you have a patient with a nut allergy to check that the product is suitable for them.
- Recommend to the patient that when purchasing, obtaining or collecting prescriptions they should always confirm that this check has been done.
- Ensure the allergy status of the patient is recorded on the patient's PMR.
- Ensure when positioning dispensing labels that important patient safety information is not obscured.



Box clearly states: CONTAINS PEANUT OIL. Do not cover with a dispensing label!

MHRA DRUG SAFETY UPDATE: VALPROATE PREGNANCY PREVENTION PROGRAMME: ACTIONS REQUIRED NOW FROM GPS, SPECIALISTS, AND DISPENSERS

Valproate medicines must not be used in women of childbearing potential unless the Pregnancy Prevention Programme is in place. This latest MHRA update on valproate

ACTIONS FOR DISPENSERS

- Valproate medicines must always be dispensed with the accompanying patient information leaflet.
- Dispense whole packs whenever possible, ensuring there is a warning label either on the carton or added via a sticker.
- Discuss risks in pregnancy with female patients each time you dispense valproate medicines and ensure they have the Patient Guide and have seen their GP or specialist to discuss their treatment and the need for contraception
- Ensure new packs of valproate information materials are placed in a designated place accessible to all dispensing staff and dispose of any old materials related to valproate medicines

(Sep 18) includes a reminder of actions required for this medicine:

All pharmacies should have received a pack of information materials for patients (a reminder of the key valproate materials and how to access them online is available in the May Drug Safety Update). If you require more copies or if you have not received a pack, please contact the Sanofi medical information department without delay on 0845 372 7101 or email UKMedicalinformation@sanofi.com.

The MHRA has produced a toolkit to ensure female patients are better informed about the risks of taking valproate medicines during pregnancy. A video for pharmacists which highlights tips on discussing valproate is also available.

TRANSDERMAL FENTANYL PATCHES: LIFE-THREATENING AND FATAL OPIOID TOXICITY FROM ACCIDENTAL EXPOSURE, PARTICULARLY IN CHILDREN


Baby died after pain relief patch became attached to her skin, inquest hears

Amelia Cooper's blood samples revealed fentanyl levels high enough to kill an adult

The MHRA has reminded health professionals that fentanyl patches may be life-threatening to children, even after use. The risks associated with fentanyl patches have been reiterated by the MHRA after a baby died when a patch worn by her mother became attached to her skin. See **here**.

Since July 2014 and up to October 2018, 5 reports of fatal incidents specifying accidental exposure, accidental overdose, or product adhesion issue have been received by the MHRA. The latest MHRA update on fentanyl patches urges all healthcare professionals, particularly those involved in the prescribing and dispensing of fentanyl patches, to **provide clear information to patients and caregivers** regarding the risk of accidental transfer and ingestion of patches, and the need for appropriate disposal of patches. Patients (and caregivers) should be advised to follow closely the instructions on the patch packaging, the carton, and in the accompanying Patient Information Leaflet.

ACTIONS FOR HEALTH CARE PROFESSIONALS

Always fully inform patients and their caregivers about directions for safe use for fentanyl patches, including the importance of:

- not exceeding the prescribed dose
- following the correct frequency of patch application, avoiding touching the adhesive side of patches, and washing hands after application
- not cutting patches and **avoiding exposure of patches to heat including via hot water (bath, shower)**
- ensuring that old patches are removed before applying a new one

- following instructions for safe storage and properly disposing of used patches or those which are not needed (see instructions below).

Ensure that patients and caregivers are aware of the signs and symptoms of fentanyl overdose (see below) and advise them to seek medical attention immediately (by dialing 999 and requesting an ambulance) if overdose is suspected

In patients who experience serious adverse events, remove patches immediately and monitor for up to 24 hours after patch removal

Report any cases of accidental exposure where harm has occurred or suspected side effects via the Yellow Card Scheme.

A useful patient information sheet has been produced by the MHRA which will help support your discussions with patients. See here.

Storage and Disposal of Fentanyl Patches
Fentanyl patches should be stored out of sight and reach of children. After use, patches should be folded so that the adhesive side of the patch adheres to itself and then placed back into the original sachet. Used patches should be kept out of sight and reach of children – even used patches contain some medicine that may harm children and may even be fatal.

Signs and Symptoms of Fentanyl Overdose
Warn patients and caregivers of possible symptoms of fentanyl overdose, which include respiratory depression (difficulty in breathing or shallow breathing); tiredness; extreme sleepiness or sedation; inability to think, walk, or talk normally; and feeling faint, dizzy, or confused. Opioid overdose can be fatal and requires urgent medical treatment.

It's Not a Choke!

The MHRA issued a reminder to healthcare professionals in July of the potential risks of airway obstruction from aspiration and choking of loose/foreign objects when inhaling pMDI. This was following a rise in reports of patients inhaling objects into the back of the throat due to inhalers being stored incorrectly without the cap in place and loose objects thus becoming trapped in the mouthpiece. Loose/foreign objects reported in these cases include tissues, stickers, coins, and plastic items. Some incidents resulted in pharyngeal injury, temporary asphyxiation, or surgical removal of aspirated objects. One patient experienced a pneumothorax.

The following advice has been issued to all healthcare professionals:

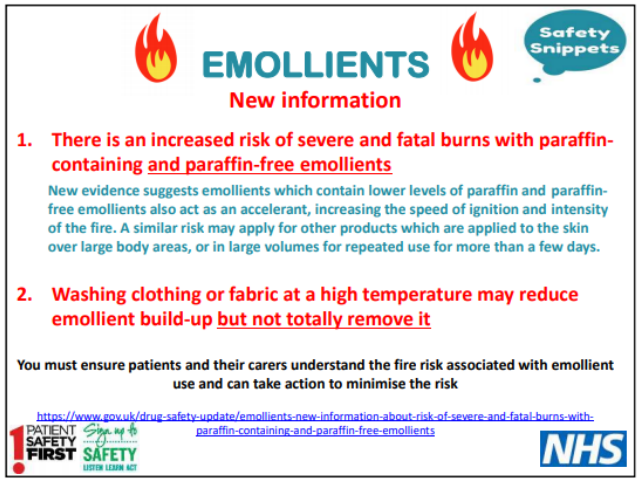
- Ensure patients are trained to correctly use their inhaler – refer to patient information leaflet for further instructions.
- Before inhaling, advise patients to remove the mouthpiece cover, shake the inhaler to remove loose/foreign objects that may be present and check the mouthpiece is clear.
- Remind patients to replace the mouthpiece immediately after use to prevent loose/foreign objects (for example, tissues, stickers, coins, plastic items) entering the mouthpiece during storage.
- Pharmacists should emphasise patients to check their pMDI for any signs of damage and to also clean their device regularly (as per manufacturer's instructions).

Emollients: NEW Information about the risk of severe and fatal burns with BOTH paraffin-containing and paraffin-free emollients

Warnings about the risk of severe and fatal burns are now being extended to **ALL** paraffin-based emollients **AND** paraffin-free emollients. See updated (Dec 18) MHRA guidance here.

Patients treated with any emollient must be made aware of the potential fire risks associated with these products which also includes emollient products used for washing and showering.

Patients who smoke or use a naked flame may cause clothing, bedding or bandages to catch fire as dressings and clothing soaked with the emollient can be easily ignited. Community pharmacy teams have an essential role to play in advising patients not to smoke; use naked flames (or be near people who are smoking or using naked flames); or go near anything that may cause a fire while emollients are in contact with their medical dressings or clothing.



What you can do to help:

- Consider your patient's smoking status prior to dispensing or applying any emollient.
- Talk to your patients about the potential fire risks of using emollient.

- Review a patient's use of emollients if they have a previous history of smoking and are displaying memory issues and/or confusion.
- Share this information with your colleagues and teams – **make sure that ALL your team are aware of the updated MHRA advice (link above).**
- If you are concerned that someone is displaying **high risk behaviours** around fire and the use of emollients, contact West Yorkshire Fire and Rescue Service for advice on 01274 682311 (ask for your local district prevention team).
- Patients displaying **high risk behaviours** around fire can also be encouraged to self-refer to West Yorkshire Fire and Rescue Service on 01274 682311 or via https://secure.westyorksfire.gov.uk:50251/public/.

The fire service will arrange to visit the person to carry out a Safe and Well visit offering support, information and appropriate interventions.

Please also take care to ensure that any flammability warnings on any products are not covered up with a dispensing label.

THE QUALITY PAYMENTS SCHEME (QPS) AND PATIENT SAFETY

The importance of patient safety is reflected in the second Quality Payments Scheme for 2018/19 with 60% of points assigned to patient safety criteria. There are now three separate elements to the patient safety criteria each worth 20 quality points each:

1. Completion of a patient safety report at premises level, identifying and managing risks with LASA errors, and uploading to any electronic reporting system and/or the National Reporting and Learning Service (NRLS)
2. Completion of CPPE Risk Management training module by 80% of registered pharmacy professionals, with a risk review example to be available at premises level.
3. Undertaking a non-steroidal anti-inflammatory drug and gastro-protection audit for patients 65 years and over

The Patient Safety Report (20 points)
To ensure you are able to identify, minimise and learn from potential errors, contractors should have a written patient safety report at premises level available for inspection at the review point on 15th February 2019.

If you engaged with this criterion at any previous Quality Payment review points you must have a new or updated report which must cover your pharmacy's analysis of incidents and patterns (taken from an ongoing log) and a record of actions taken in response to patient safety alerts.

You will also be required to demonstrate that you have actively identified and managed risks of look-alike sound-alike errors (LASAs) identified from the National Reporting & Learning System (NRLS). Top combinations by likelihood and harm are:

- Propranolol and Prednisolone.
- Amlodipine and Amitriptyline.
- Carbamazepine and Carbimazole,
- Azathioprine and Azithromycin
- Atenolol and Allopurinol

For these combinations you need to show what actions have been taken to reduce risk (e.g. physical separation, raising staff awareness, visual warnings, tags or labels on shelves, enhanced checking procedures for these medicines).

Additionally you are required to upload any LASA incident reports to the NRLS (see below).

Reporting Errors to the NRLS
Contractors already have a contractual requirement to report patient safety incidents to the National Reporting and Learning System. This can be done via the e-form following guidance on the PSNC website, and some contractors collate reports via corporate systems, which then report centrally to NRLS. When LASA incidents are reported to NRLS directly or via other systems, in the description of what happened in the incident, 'LASA' should be included. This will enable NHS Improvement to search for LASA-related reports and information and learning from such incidents can be maximised.

Copies of patient safety incident reports made by a pharmacy to NRLS or to corporate or other incident reporting systems should be retained by the contractor.

Resources (Patient Safety Report)
- Available resources for the patient safety report criterion include monthly and annual patient safety report templates produced by PSNC and the Community Pharmacy Patient Safety Group. See here.
- The NPA have launched a "look-alike sound alike" list which may be helpful for contractors.
- The PSNC's patient safety information page contains a list of patient safety alerts, advice and guidance and MHRA monthly drug safety updates and is useful as a quick reference guide for pharmacy teams to check that they are aware of all these and have taken appropriate action when required.
- Use this newsletter as an opportunity for you to share your learning from incidents or near misses that have occurred locally

Risk Management (20 points)
You must have an example of a risk review (undertaken by the pharmacy team).

The pharmacy team at the premises must have completed the risk review, for a risk in their pharmacy, that has been identified and prioritised with identified risk minimisation actions that the pharmacy team is taking. See here for further information. PSNC and the Community Pharmacy Patient Safety Group have produced a number of resources to assist community pharmacy contractors with meeting the risk review part of the risk management quality criterion - see here.

To meet the risk management criterion, on the day of the review, 80% of your registered pharmacy professionals (e.g. pharmacists and pharmacy technicians) must have satisfactorily completed the CPPE Risk Management training – see here..

NSAID and Gastro Protection Audit (20 points)
To achieve this criterion you must complete the audit of non-steroidal anti-inflammatory drugs (NSAIDs) and gastro-protection for patients aged 65 and over - see here.

Data must be collected for two weeks with a minimum of ten patients participating in the audit. All patients aged 65 years or over who present a prescription for any oral NSAID or COX2 selective inhibitor (this does not include patients prescribed aspirin) should be included in the audit. In cases where there is difficulty in finding ten patients to participate, the audit should be extended to four weeks after which contractors can submit the data with the number of patients they have if less than ten.

Data must be submitted by the February review point (15th February 2019) in order to meet this quality criterion.

See here for further information.

INCIDENT SHARING

The following are summaries of some of the medicines safety incidents which have been reported from our local pharmacy teams. THANK YOU to everyone that has shared details of their incidents with us. This will hopefully benefit other local pharmacies by helping to avoid the same errors happening again, and thus potentially helping to avert patient harm.

- **Wrong drug/medicine (LASA) –** a prescription for clonazepam 0.5 mg was dispensed. The pharmacy dispensed what was in stock and gave an owing for the balance. When the balance was dispensed, clonidine was given in error. These tablets are next to each other on the shelf and have similar names and dosing. Additionally, there had been no dispenser check done and the pharmacist had just checked a prescription for clonidine so this was still on their mind. The pharmacy reviewed the incident and have now separated the packs and added a note to check.

Community Pharmacy West Yorkshire Comment – Please exercise caution when dispensing any medicines with similar names and/or packaging. As the pharmacy that reported this incident has done, it is important that you analyse errors which have occurred in your pharmacy and draw up a list of medicines which have been commonly involved in errors especially those with similar sounding names and similar packaging. Ensure that all members of the pharmacy team are aware of this list and take additional care when dispensing them. Take steps to minimise the risk of further errors with these medicines, for example by separating the products on the dispensary shelves, or by using labels to highlight on the shelf edge. REMEMBER TO KEEP EVIDENCE OF THIS AND REPORT ANY LASA incidents TO THE NRLS (see section on Quality Payments).

Bitesize Chunks

Methotrexate & Trimethoprim – Trimethoprim should never be given to patients on methotrexate
A quick reminder of the potentially serious interaction between methotrexate and trimethoprim. The interaction has the potential to cause catastrophic patient harm even with short courses or low doses of trimethoprim and **trimethoprim must therefore never be prescribed to a patient on methotrexate.** Pharmacists must not dispense these drugs in combination and must always query the co-prescription of methotrexate and trimethoprim directly with the prescriber (be aware that co-trimoxazole (Septrin®) contains trimethoprim. Methotrexate interacts with a significant number of other medicines. If you are aware that a patient is on methotrexate it is essential that you check for interactions when dispensing any new medicines.

METHOTREXATE = ONCE A WEEK DOSING

- Prescribing and dispensing errors with methotrexate continue to cause the most harm. Always double-check prescriptions: right strength ✓ right dose ✓ right frequency = weekly ✓
- Clearly explain the dosing schedule to patients, i.e. once weekly, on the same day each week.
- Ensure labelling is clear, e.g. Take EIGHT tablets ONCE weekly (on the same day each week).
- Tell patients to report adverse reactions and contraindications
- Be aware of interactions that increase the risk of toxicity

Minutes to Better Inhaler Technique - Asthma UK and the UK Inhaler Group have created a new collection of easy to watch videos showing best practice inhaler technique, covering all the major brands of inhalers. See here.

Drug Safety Updates (MHRA)

Contents of recent Drug Safety Updates are listed below. Where this has particular relevance to community pharmacy this has been highlighted in red and a summary of the advice provided. For further information about any of these updates refer to MHRA Drug Safety Updates in full by clicking here.

July 2018 (click here for July Drug Safety Update)

- Darunavir boosted with cobicistat: avoid use in pregnancy due to risk of treatment failure and maternal-to-child transmission of HIV-1
- **Pressurised metered dose inhalers (pMDI): risk of airway obstruction from aspiration of loose objects.** This has been covered in the body of the newsletter – see above.
- Eltrombopag (Revolade): reports of interference with bilirubin and creatinine test results
- Parenteral amphotericin B: reminder of risk of potentially fatal adverse reaction if formulations confused
- Medicines taken during pregnancy: please report suspected adverse drug reactions, including in the baby or child, on a Yellow Card.

August 2018 (click here for August Drug Safety Update)

- Esmya (ulipristal acetate) and risk of serious liver injury: new restrictions to use and requirements for liver function monitoring before, during, and after treatment (note – these new measures are for women receiving Esmya for the treatment of uterine fibroids. The emergency contraceptive EllaOne also contains ulipristal acetate in a single dose of 30 mg. The Drug Safety Update reports that no cases of serious liver injury have been reported with EllaOne and there are no concerns or changes to its use at this time. For further information please refer to the Drug Safety Update (link above).

September 2018 (click here for September Drug Safety Update)

- **Valproate Pregnancy Prevention Programme: actions required now from GPs, specialists, and dispensers.** This has been covered in the body of the newsletter – see above.
- Xofigo▼ (radium-223-dichloride): new restrictions on use due to increased risk of fracture and trend for increased mortality seen in clinical trial
- Daclizumab beta (Zinbryta▼): risk of immune-mediated encephalitis – some cases several months after stopping treatment
- Nusinersen (Spinraza▼): reports of communicating hydrocephalus; discuss symptoms with patients and carers and investigate urgently

October 2018 (click here for October Drug Safety Update)

- Rivaroxaban (Xarelto▼) after transcatheter aortic valve replacement: increase in all-cause mortality, thromboembolic and bleeding events in patients in a clinical trial.
- Ritonavir-containing products: reports of interaction with levothyroxine leading to reduced thyroxine levels page 4 Ponatinib (Iclusig▼): reports of posterior reversible encephalopathy syndrome.
- **Transdermal fentanyl patches: life-threatening and fatal opioid toxicity from accidental exposure, particularly in children.** This has been covered in the body of the newsletter – see above.

The PSNC's patient safety information page contains a list of patient safety alerts, advice and guidance and MHRA monthly drug safety updates and is useful as a quick reference guide for pharmacy teams to check that they are aware of all these and have taken appropriate action when required.

If you have any feedback, suggestions or wish to include anything in our next newsletter please email info@cpwy.org. Thank you