The T@blet

News from the Medicines Management Team

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PRIORITY INFORMATION

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

Provide clear information to patients and caregivers about how to minimise the risk of accidental exposure and the importance of appropriate disposal of patches. Advice for healthcare 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
- ensure that patients and caregivers are aware of the signs and symptoms of fentanyl overdose 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

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and monitor for up to 24 hours after patch removal

HYDROCHLOROTHIAZIDE: RISK OF NON-MELANOMA SKIN CANCER, PARTICULARLY IN LONG-TERM USE

Advise patients taking hydrochlorothiazide-containing products of the cumulative, dose-dependent risk of non-melanoma skin cancer, particularly in long-term use, and the need to regularly check for (and report) any suspicious skin lesions or moles.

Counsel patients to limit exposure to sunlight and UV rays and to use adequate sun protection.

Advice for healthcare professionals:

- pharmacoepidemiological studies have shown a dose-dependent increased risk of non-melanoma skin cancer (basal cell carcinoma [BCC] and squamous cell carcinoma [SCC], including SCC lip cancer) with exposure to increasing cumulative doses of hydrochlorothiazide
- inform patients taking hydrochlorothiazide-containing products of the risk of nonmelanoma skin cancer, particularly in long-term use, and advise them to regularly check for and report any new or changed skin lesions or moles
- reconsider the use of hydrochlorothiazide in patients who have had previous skin cancer
- examine all suspicious moles or skin lesions (potentially including histological examination of biopsies)
- advise patients to limit their exposure to sunlight and UV rays and use adequate protection when exposed to sunlight and UV rays to minimise the risk of skin cancer

ADRENALINE AUTO INJECTORS

MHRA Drug Safety Update, August 2017 recommends that healthcare professionals should prescribe two adrenaline auto-injectors (AAIs) to adults and children with allergies who are at risk of having a severe allergic reaction (anaphylaxis). The guidance also recommends that people should carry their two AAI devices on them at all times. The CCG medicines management group supports the 2 device per patient position.

Guidance from the Department of Health and Social Care, which was issued to schools last year, states that from 1 October 2017 schools in England are allowed to purchase AAI devices without a prescription, for emergency use on children who are at risk of anaphylaxis but whose own device is not available or not working.

Therefore schools are responsible for purchasing their own emergency stocks of AAIs and no additional AAIs will be prescribed by GPs for storage at school.

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REGULAR INFORMATION

TAPENTADOL (PALEXIA): RISK OF SEIZURES AND REPORTS OF SERATONIN SYNDROME WITH OTHER MEDICINES

Tapentadol may increase seizure risk in patients taking other medicines that lower seizure threshold, for example, antidepressants and antipsychotics. Serotonin syndrome has also been reported when tapentadol is used in combination with serotoninergic antidepressants.

Advice for healthcare professionals:

- as for all opioid medicines, tapentadol can induce seizures
- tapentadol should be prescribed with care in patients with a history of seizure disorders or epilepsy
- tapentadol may increase seizure risk in patients taking other medicines that lower seizure threshold, for example, antidepressants such as serotonin reuptake inhibitors (SSRIs), serotonin-noradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants, and antipsychotics
- serotonin syndrome has been reported when tapentadol is used in combination with serotoninergic antidepressants (see typical presenting symptoms below)
- withdrawal of the serotoninergic medicine, together with supportive symptomatic care, usually brings about a rapid improvement in serotonin syndrome
- report suspected adverse drug reactions, including those resulting from interactions between drugs, on a Yellow Card

Reports of serotonin syndrome

We are also aware of reports of serotonin syndrome identified when tapentadol is coadministered with antidepressants, such as serotonin reuptake inhibitors (SSRIs), serotoninnoradrenaline reuptake inhibitors (SNRIs), tricyclic antidepressants and antipsychotics. Serotonin syndrome is likely when one of the following is observed:

- Spontaneous clonus
- Inducible or ocular clonus with agitation or diaphoresis (sweating)
- Tremor and hyperreflexia
- Hypertonia and body temperature higher than 38°C and inducible ocular clonus

Withdrawal of the serotoninergic medicine together with supportive symptomatic care, usually brings about a rapid improvement. The continued use of tapentadol must be evaluated on an ongoing basis. Withdrawal symptoms can occur with abrupt cessation of treatment.

See the Summary of Product Characteristics for tapentadol for details of other interactions, including advice to avoid monoamine oxidase inhibitors with tapentadol because of the potential for hypertensive crisis.

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SYSTEMIC AND INHALED FLUROQUINOLONES: SMALL INCREASED RISK OF AORTIC ANEURYSM AND DISSECTION: ADVICE FOR PRESCRIBING IN HIGH-RISK PATIENTS

In patients at risk for aortic aneurysm and dissection, fluoroquinolones should only be used after careful assessment of the benefits and risks and after consideration of other therapeutic options.

Fluoroquinolone medicines available in UK

- Ciprofloxacin
- Levofloxacin
- Moxifloxacin
- Ofloxacin

Advice for healthcare professionals:

- systemic (by mouth or injection) and inhaled fluoroquinolones may be associated with a small increased risk of aortic aneurysm and dissection, particularly in older patients
- fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients at risk for aortic aneurysm and dissection
- Conditions predisposing to aortic aneurysm and dissection include:
 - a family history of aneurysm disease
 - diagnosis with pre-existing aortic aneurysm and/or aortic dissection
 - other risk factors or conditions predisposing for aortic aneurysm and dissection (for example, Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, and known atherosclerosis)
 - advise patients, particularly elderly people and those at risk, about rare events of aortic aneurysm and dissection and of the importance of seeking immediate medical attention in case of sudden-onset severe abdominal, chest or back pain.