Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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Drug Assessments

Product	Summary	Decision
Pentosan polysulfate sodium 100mg capsules (Elmiron®)	**Introduction:** Pentosan is now available as a licensed product Pentosan polysulfate sodium 100mg capsules (Elmiron). This now replaces unlicensed formulations of pentosan. It is licensed for the treatment of bladder pain syndrome characterized by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition. When other interventions (topical sodium hyaluronate +/- sodium chondroitin) have been unsuccessful **Further relevant information:** The licensed formulation of pentosan must be used in preference to any unlicensed formulations. Patients currently receiving treatment with unlicensed pentosan should be switched to the licensed formulation. PACEF has acknowledged that the cost of the licensed formulation is higher than that for the unlicensed formulation, however MHRA advice must be followed and a licensed product used where available. Due to the availability of the licensed formulation ULHT have requested that pentosan (Elmiron®) is reclassified as an AMBER 2 drug. It is considered appropriate for prescribing in primary care following initiation by or on the advice of a specialist.	Pentosan polysulfate sodium 100mg capsules (Elmiron) is approved for inclusion onto the formulary classed as AMBER 2. Unlicensed formulation of Pentosan are reclassified as RED/RED and removed from the formulary.
Oxypro® – prolonged release oxycodone	**Introduction** The price of Oxypro® has been reduced to that of Oxeltra®. This means there are now two brands of prolonged release oxycodone available at a significantly lower cost compared to alternative formulary approved products. Oxycodone is included on the formulary as a second line opioid when morphine sulphate is not an appropriate choice. **Further relevant information** Available in a range of strengths 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg. Oxypro® was approved as an alternative first-line choice along with Oxeltra® when use of prolonged release formulations of oxycodone is considered clinically appropriate. Patients currently receiving alternative brands of oxycodone prolonged release should be reviewed and switched to either Oxypro® or Oxeltra® where possible.	Approved for inclusion onto the formulary as GREEN. To maximise potential savings prescribe by brand.

Discontinuation of Zovirax (acyclovir) 3% eye ointment

GSK the sole provider of acyclovir eye ointment have announced that it will be discontinued worldwide. Stock is anticipated to continue to be available in the UK until the end of June 2019, subject to demand.
On the Lincolnshire Formulary acyclovir eye ointment 3% is currently the first-line antiviral for use in the eye.
Ganciclovir 0.15% eye gel (Virgan) is listed as a second line choice antiviral. It was previously approved to be used as an alternative to acyclovir, when there were disruptions in the supply of acyclovir.
ULHT have stated that once supplies of acyclovir eye ointment have been exhausted then ganciclovir, as the only licensed antiviral, will become the antiviral of choice.

MEDICINES AND HEALTHCARE REGULATORY AGENCY (MHRA): DRUG SAFETY UPDATE (November 2018)

Hydrochlorothiazide: risk of non-melanoma skin cancer, particularly in long-term use

Hydrochlorthiazide containing formulations are classed as Non-Formulary RED/RED although scrutiny of prescribing data has shown some use across the county.

The issuing of advice from the MHRA of the risk of skin cancers associated with long term use should prompt a review of these patients with the aim to switch alternative thiazide and related diuretics, where appropriate.

MHRA have issued the following 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.
- Clinicians should inform patients taking hydrochlorthiazide contanong products of the risk of non-melanoma 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 hydrochlorthiazide in patients who have had previous skin cancer.
- Examine all suspicious mole 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.
- Report any suspected adverse reactions to medicines on a yellow card.

Systemic and inhaled fluroquinolones: Small increased risk of aortic aneurysm and dissection; advice for prescribing in high-risk patients

Fluoroquinolones antibiotics available in the UK are ciprofloxacin, levofloxacin, moxifloxacin and ofloxacin. All four fluroquinolones are included on the Lincolnshire formulary.
Data from epidemiologic and non-clinical studies indicate an increased risk of aortic aneurysm and dissection after intake of fluroquinolones.

MHRA have issued the following advice for healthcare professionals:

- Systemic (by mouth or injection) and inhaled fluroquinolones may be associated with a small increased risk of aortic aneurysm and dissection, particularly in older patients
- Fluroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients at risk of 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 for example Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension and known atherosclerosis.
    - Advise patients, particularly elderly patients and those at risk, about rare adverse events and the importance of seeking immediate medical attention in case of sudden-onset severe abdominal, chest or back pain.
    - Report any suspected adverse reactions to fluroquinolone antibiotics on a yellow card.

MEDICINES AND HEALTHCARE REGULATORY AGENCY (MHRA): DRUG SAFETY UPDATE (December 2018)

Valproate medicines: are you in compliance with the pregnancy prevention measures

The MHRA have reported that although use of valproate medicines in female patients continues to slowly decline, there are still reports that women have not received patient information with their dispensed valproate medicines.

The MHRA have issued the following advice and information for healthcare professionals:

- Valproate should not be used in women and girls of childbearing potential unless there is no suitable alternative and the conditions of the pregnancy Prevention Programme are met.
- Although use in female patients in the UK continues to slowly decline, data shows a wide geographical variation in the prescribing of valproate medicines.
- Women continue to report instances when pharmacists have not provided a patient information leaflet or Patient Card when dispensing.
- Ensure you are complying with the responsibilities of healthcare professionals involved in the care of female patients on valproate – including when valproate is used outside the licensed indications.
- An audit function is available on all GP software systems – this should be used to identify and recall all women and girls on valproate who may be of childbearing potential and refer to an appropriate specialist for a review.

Emollients: new information about risk of severe and fatal burns with paraffin containing and paraffin- free emollients

Warnings are being extended to cover all paraffin based emollients regardless of concentration.

MHRA have issued the following advice for healthcare professionals:

- You must ensure patients and their carers understand the fire risk associated with the build-up of residue on clothing and bedding and can take action to minimise the risk.
- When prescribing, recommending, dispensing, selling or applying emollient products to patients, instruct them not to smoke or go near naked flames because clothing or fabric such as bedding or bandages that have been in contact with an emollient or emollient treated skin can rapidly ignite.
- There is a fire risk with all paraffin containing emollients regardless of paraffin concentration and also cannot be excluded with paraffin free emollients. A similar risk may apply to other products which are applied to the skin over large body areas, or in large volumes for repeated use for more than a few days.
- Be aware that washing clothing or fabric at high temperatures may reduce emollient build up, but not totally remove it.
- Warnings including an alert symbol are being added to packaging to provide a visual reminder to patients and those caring for them about the fire hazard.
- Report any fire incidents with emollients or other skin care products to the yellow card scheme.

Hydrocortisone muco-adhesive buccal tablets: should not be used off-label for adrenal insufficiency in children due to serious risks.

MHRA have issued the following advice for healthcare professionals:

- Hydrocortisone muco-adhesive buccal tablets are indicated only for local use in the mouth for aphthous ulceration and should not be used for treating adrenal insufficiency.
- Substitution of licensed oral formulations of hydrocortisone with muco-adhesive buccal tablets can result in insufficient cortisol absorption and in stress situations, life threatening adrenal crisis.
- Prescribers and pharmacists should only consider use of licensed hydrocortisone products for adrenal replacement therapy.
- Report suspected adverse drug reactions, including medication errors resulting in harm on a Yellow Card.

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