

## Medicines Safety Assurance Tool

August 2020

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)



Midlands and Lancashire  
Commissioning Support Unit

### Safe use of emollient skin creams to treat dry skin conditions

03 August 2020

Dried-on emollients, transferred from skin onto clothing, bedding and bandages, have been shown to make fabric more flammable. The resulting fire may result in serious injury or death, therefore the MHRA is warning for anyone using emollients to avoid any naked flame/smoking.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

### Steroid Emergency Card To Support Early Recognition And Treatment Of Adrenal Crisis In Adults

10 August 2020

The alert asks providers to ensure all eligible patients are issued with a Steroid Emergency Card; and to put processes in place to check if a patient has a Steroid Emergency Card ahead of any emergency treatment, elective surgery, or other invasive procedures.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

## Medicines Safety Assurance Tool

August 2020

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)

### [NPSA Rapid Response Report: Preventing fatalities from medication loading doses. A UKMI risk assessment tool to support local implementation](#)

17 August 2020

This updated document, which supports the NPSA rapid response report on preventing fatalities from medication loading doses, provides a comprehensive list of medications for which a loading dose is given in routine clinical practice.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Unassigned ▼

Action due date

Date completed

### [Lithium Carbonate \(Priadel\) 200mg And 400mg Modified Release Tablets - Supply Disruption](#)

21 August 2020

Priadel® (lithium carbonate) 200mg and 400mg modified-release tablets are being discontinued in the UK and remaining supplies of both strengths are expected to be exhausted by April 2021. This alert contains advice on the management of impacted patients.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Unassigned ▼

Action due date

Date completed

## Medicines Safety Assurance Tool

August 2020

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)

### Isotretinoin (Roaccutane ▼): reminder of important risks and precautions

26 August 2020

We remind healthcare professionals that isotretinoin should only be used for severe forms of acne resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy. Prescription of isotretinoin should be supervised by specialist dermatologists with a full understanding of the potential risks and monitoring requirements.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

### Emollients and risk of severe and fatal burns: new resources available

26 August 2020

We inform healthcare professionals of the recent campaign to promote awareness of the risk and new resources available to support safe use following previous advice to health and care professionals.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

## Medicines Safety Assurance Tool

August 2020

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)

### Leuprorelin-containing depot products

26 August 2020

Need to strictly follow instructions for reconstitution and administration to reduce the risk of handling errors that may result in lack of efficacy.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

## Summary of Product Characteristics updates

### **ABASAGLAR (insulin glargine) 100 units/mL solution for injection in a pre-filled pen and cartridge**

Injection technique information has been expanded in SPCs to advise continuous rotation of injection site to reduce risk of lipodystrophy and cutaneous amyloidosis and warn of potential risk of delayed insulin absorption following insulin injections at sites with these reactions.

### **Aripiprazole 1 mg/ml Oral Solution**

A guide for healthcare professionals and a guide for patient/caregiver provide detailed information of how to use this medicine and what to expect during treatment including potential adverse reactions.

### **Boostrix-IPV (diphtheria, tetanus, pertussis, poliomyelitis) suspension for injection in pre-filled syringe**

SPC notes, if in accordance with official recommendations, the vaccine may be administered subcutaneously to subjects with thrombocytopenia. With both routes of administration, firm pressure should be applied to the injection site (without rubbing) for at least two minutes

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

## Medicines Safety Assurance Tool

August 2020

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)

Midlands and Lancashire  
Commissioning Support Unit

pressure should be applied to the injection site (without rubbing) for at least two minutes.

### **Botox (Botulinum toxin type A) powder for solution for injection**

Eyelid oedema has been added as a potential uncommon adverse effect of treatment

### **Buccolam (midazolam) oromucosal solution**

Angioedema has been added as a potential adverse effect of treatment (unknown frequency).

### **Clomid (clomifene citrate) 50mg Tablets**

SPC warns of rare reports of ovarian cancer with fertility drugs; infertility itself is a primary risk factor.

### **Co-cyprindiol (cyproterone acetate, ethinylestradiol) tablets**

SPC warns and contraindicates use in meningiomas (single and multiple) which have been reported in association with use of cyproterone acetate, especially at high doses of 25 mg and above and for prolonged time.

### **Colestid (colestipol) granules for oral suspension**

Information on colestipol affecting the absorption of chlorothiazide has been added to the SPC. It also notes that colestipol may reduce mycophenolic acid exposure and potentially reduce efficacy of mycophenolate mofetil.

### **Colobreathe (colistimethate sodium) inhalation powder – Patient card**

This instructional video provides information on how to load the Colobreathe Turbospin inhaler, how to inhale the medicine and inspect and clean the device to reduce risk associated with use of treatment.

### **Cymbalta (duloxetine) hard gastro-resistant capsules**

The pregnancy section has been updated with data from two large observational studies (one EU and one US); these do not suggest an overall increased risk of major congenital malformation, but the analysis on specific malformations is inconclusive.

### **Dalacin T (clindamycin) Topical Solution**

Although post-marketing studies have indicated a very low incidence of pseudomembranous colitis with Dalacin T Lotion, the physician should be alert to the development of antibiotic-associated diarrhoea or colitis, and it should be stopped immediately if diarrhoea occurs.

### **DuoResp Spiromax (budesonide/formoterol) inhalation powder- all strengths**

Dysphonia including hoarseness has been added to SPCs as a common adverse effect.

## Medicines Safety Assurance Tool

August 2020

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)

### Efudix (fluorouracil) 5% Cream

SPC updated with reports of increased toxicity in patients who have reduced activity of dihydropyrimidine dehydrogenase, a key enzyme involved in metabolising and eliminating fluorouracil. In the event of suspected systemic drug toxicity, treatment should be stopped.

### Eliquis (apixaban) 2.5 and 5.0 mg film-coated tablets

Angioedema has been added as an adverse drug reaction of unknown frequency.

### Fluarix Tetra (influenza) suspension for injection in pre-filled syringe

SPC details that this vaccine complies with the WHO recommendation (northern hemisphere) and EU recommendation for the 2020/2021 season.

### Insulin lispro; Insuman Infusat/Comb/Rapid (human insulin) and Toujeo (insulin glargine)

SPCs have been updated to advise insulin absorption may vary from one injection area to another (e.g. abdominal wall vs. thigh) and injection sites within an injection area must be rotated from one injection to next in order to reduce risk of lipodystrophy & cutaneous amyloidosis.

### Insuman Basal (human insulin) products

SPCs have been updated to advise insulin absorption may vary from one injection area to another (e.g. abdominal wall vs. thigh) and injection sites within an injection area must be rotated from one injection to next in order to reduce risk of lipodystrophy & cutaneous amyloidosis.

### Jardiance (empagliflozin) film-coated tablets – all strengths

SPCs updated to advise co-treatment with known inducers of uridine 5'-diphosphoglucuronosyltransferase (e.g. rifampicin or phenytoin) is not recommended due to potential risk of decreased efficacy of empagliflozin.

### Keppra (levetiracetam) products

SPC now warns that as with other antiepileptics, levetiracetam may rarely exacerbate seizure frequency/severity. This paradoxical effect was mostly reported within 1st month after start of treatment or increase of dose and was reversible upon drug discontinuation or dose decrease.

## Medicines Safety Assurance Tool

August 2020

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)

Midlands and Lancashire  
Commissioning Support Unit

### Lantus preparations

SPC now emphasises that patients must continuously rotate the injection site to reduce the risk of lipodystrophy and cutaneous amyloidosis. There is a risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions.

### Monuril (fosfomycin) 3g granules for oral solution

Use is now contraindicated in severe renal insufficiency (creatinine clearance < 10 ml/min) and haemodialysis. Based on safety and efficacy data which do not indicate any malformative or foetal/neonatal toxicity, use may be considered during pregnancy, if necessary.

### Plaquenil-Hydroxychloroquine sulfate tablets

SPC now adds detail with respect to several drug interactions; it can increase digoxin levels, enhance the effects of hypoglycaemic treatment and increase ciclosporin levels. It is also now contraindicated with drugs known to induce retinal toxicity, e.g. tamoxifen.

### Plavix (clopidogrel) film-coated tablets

Sections 4.4 and 4.5 have been updated with information on a drug-drug interaction with rifampicin and clopidogrel, based on a literature review and a review of the marketing authorisation holder's pharmacovigilance database.

### Qutenza (capsaicin) 179mg cutaneous patch

SPC revised to advise re-treatment after less than 90 days can be considered for individual patients only after a careful assessment by the physician. A minimum interval of 60 days between treatments is to be observed.

### Restandol Testocaps (testosterone undecanoate) 40 mg capsule, soft

SPC has been updated to advise that Restandol Testocaps contains castor oil, which may cause stomach upset and diarrhoea.

### Solu-Cortef (hydrocortisone sodium succinate)

SPC has been updated to warn that hypertrophic cardiomyopathy has been reported after administration of hydrocortisone to prematurely born infants, therefore appropriate diagnostic evaluation and monitoring of cardiac function and structure should be performed.

## Medicines Safety Assurance Tool

August 2020

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)

Midlands and Lancashire  
Commissioning Support Unit

### Viagra Connect (sildenafil citrate)

The guide for supply of Viagra includes important considerations when assessing men as suitable candidates for treatment e.g. understanding erectile dysfunction and provides case study examples. The pharmacy checklist helps to assess men's suitability for treatment.

### Ventolin (salbutamol) Syrup

SPC has been updated to warn that potentially serious hypokalaemia may be potentiated by concomitant treatment with diuretics.

### Zocor (simvastatin) film-coated tablets- all strengths

The following adverse events have been added to SPCs: blurred vision and visual impairment (rare), lichenoid drug eruptions (very rare), muscle rupture (very rare), and gynecomastia (very rare).