Medicines Safety Assurance Tool

September 2022

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

Midlands and Lancashire Commissioning Support Unit

Regulation 28 report to prevent future deaths

20 September 2022

Concerns include systematic review for all patients receiving repeat prescriptions of multiple analgesics to formulate individual plans.

Proposed action

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

Action taken

Status | Action due date | Date completed

Safety considerations when using Vitamin D

07 September 2022

The number of available products has resulted in variability of clinical guidance in recommended reference sources and clinical use. Healthcare professionals who should be aware of the risks of toxicity and safe practice principles which may prevent patient harm.

Proposed action

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

Action taken

Status | Action due date | Date completed

Methylphenidate long-acting (modified-release) preparations: caution if switching between products due to differences in formulations

26 September 2022

Prescribers and dispensers should use caution if switching patients between different long-acting formulations of methylphenidate (Concerta XL, Medikinet XL, Equasym XL, Ritalin LA, and generics) as different instructions for use and different release profiles may affect symptom management.

Proposed action
- [x] Newsletter
- [ ] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other (please specify)

Action taken

Status | Action due date | Date completed

Summary of Product Characteristics updates

Amfexa (dexamfetamine sulfate) Tablets – all strengths

SPC updated in line with PRAC recommendations and now notes amfetamines can cause a significant elevation in plasma corticosteroid levels; this increase is greatest in the evening & amfetamines may interfere with urinary steroid determinations.

Proposed action
- [x] Newsletter
- [ ] Optimise Rx/ScriptSwitch
- [ ] Practice audit/search
- [ ] Other (please specify)

Action taken

Status | Action due date | Date completed

Arthrotec 75 modified release tablets (diclofenac and misoprostol)

The SPC has been updated to include hydrogenated castor oil as an excipient and to state that this substance may cause stomach upset and diarrhoea.

Boostrix-IPV [diphtheria, tetanus, pertussis (acellular) and poliomyelitis (inactivated)] suspension for injection in pre-filled syringe

Information and warnings related to potassium, sodium, formaldehyde, para-aminobenzoic acid and phenylalanine content has been added to the SPC.

Bydureon (exenatide) 2 mg prolonged release suspension for injection in pre-filled pen (BCise)
Cholecystitis and cholelithiasis have been added to SPC as uncommon adverse effects.

Forxiga (dapagliflozin) film-coated tablets
Dapagliflozin may increase renal lithium excretion and decrease blood lithium levels. Serum lithium concentration should be monitored more frequently after dapagliflozin initiation and dose changes. Tubulointerstitial nephritis has been added as an adverse drug reaction.

Gabitril (tiagabine) tablets
SPC updated with reports of amnesia (frequency not known) and further information on hospitalisation in the event of an overdose.

Imodium (loperamide) preparations
Acute pancreatitis has been added as a rare potential adverse effect of treatment and caution now advised when used in patients with a history of drug abuse, due to reports of abuse and misuse of loperamide.

Jaydess (levonorgestrel) 13.5 mg intrauterine delivery system
SPC updated in line with levonorgestrel PSUR outcome, including additional information to address onset of contraceptive efficacy & minimise risk of insertion after conception. A table has been added to section 4.2 to clarify when to insert Jaydess in women of fertile age.

Jayempi (azathioprine) 10mg/ml oral suspension
SPC updated with addition of chromaturia as an adverse effect with unknown frequency and corresponding advice that chromaturia often presents as bright yellow urine, and may occur independent of, or because of, renal or hepatic disorder.

Mirena (levonorgestrel) 20 micrograms/24 hours intrauterine delivery system
Additional information to address the onset of contraceptive efficacy and to minimise the risk of insertion after conception has been added to the SPC (additionally to the Kyleena [levonorgestrel] 19.5 mg intrauterine delivery system SPC).

Nexplanon (etonogestrel) 68 mg implant for subdermal use
The SPC has been updated to include missing information on the adverse reaction vasovagal reactions with implant insertion.

Paludrine/Avloclor Anti-Malarial Travel Pack Chloroquine & Proguanil Anti-Malarial Tablets
SPC updated with addition of warning of potential increased risk of cardiovascular (CV) events and CV mortality with use of chloroquine with macrolide antibiotics and hydroxychloroquine with azithromycin. Benefits and risks should be considering carefully before co-prescribing.

Sildenafil tablets
SPC notes that sildenafil, can significantly potentiate the hypotensive effect of sacubitril/valsartan. Therefore, caution should be exercised when using sildenafil with sacubitril/valsartan.

Spikevax Covid-19 vaccine
Shelf-life instructions (sections 6.3 & 6.4) have been updated, with the storage instructions changed from "-25ºC to -15ºC" to "-50ºC to -15ºC.

Syonell (valproate semisodium) 250 and 500mg Gastro-Resistant Tablets
SPC includes its other name, divalproex sodium, and now notes fertility dysfunctions are in some cases reversible ≥3 months after treatment discontinuation. Limited data suggest strong dose reduction may improve fertility. In some cases, reversibility of male infertility unknown.

Topamax (topiramate) preparations
In section on acute myopia & secondary angle closure glaucoma syndrome that has been reported in patients receiving topiramate, other ophthalmologic findings of this syndrome have been added (mydriasis choroidal detachments, retinal pigment epithelial detachments, macular striae).

Zintasa (mesalazine) 400mg Tablets
SPC now notes that Zintasa is contraindicated in children under the age of 2 years and there are no longer any dosage recommendations for children aged from 2-17 years.

About this document

MLCSU collates and shares the latest current awareness and evidence-based medicines information from NICE and UKMi relating to medicines safety each month.

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