Medicines Safety Assurance Tool

July 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

NHS Midlands and Lancashire Commissioning Support Unit

Hydroxychloroquine and chloroquine retinopathy monitoring

08 July 2022

This document, produced by the Regional Medicines Optimisation Committee (South), outlines the risks of retinopathy and contains practical recommendations for safe ophthalmology monitoring of patients who are receiving long term hydroxychloroquine or chloroquine therapy.

Proposed action

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

Action taken

Status | Action due date | Date completed

Topiramate (Topamax): start of safety review triggered by a study reporting an increased risk of neurodevelopmental disabilities in children with prenatal exposure

21 July 2022

MHRA have initiated new safety review into topiramate as a result of an observational study reporting increased risk of neurodevelopmental disabilities in children whose mothers took it during pregnancy. Patients need counselling on this risk & on need for effective contraception.

Proposed action

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

Action taken

Status | Action due date | Date completed

Risk Minimisation Materials

Apixaban patient alert card

Patient alert card includes information on the possible side effects of treatment and advises when to contact their doctor immediately, and symptoms for which they should stop treatment immediately and seek medical help.

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

Avloclor (chloroquine) Tablets

SPC updated to note the benefits and risks should be considered before prescribing chloroquine for any patients taking macrolide antibiotics, because of the potential for an increased risk of cardiovascular events and cardiovascular mortality.

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

Action taken

Brinzolamide/Timolol Mylan 10 mg/ml + 5 mg/ml eye drops, suspension

SPC updated to note that the same types of adverse drug reactions that are attributable to sulphonamides may occur with topical administration of brinzolamide, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

epidermal necrolysis.

Status	Action due date	Date completed

Canesten (clotrimazole) pessaries, vaginal capsules, creams, sprays and solution

SPC now includes information on an interaction with tacrolimus (may lead to increased tacrolimus plasma levels), an updated recommendation allowing use during pregnancy (under supervision) and breastfeeding, and addition of new adverse events.

Canesten Thrush (clotrimazole) vaginal use preparations

Anaphylactic reactions (rare), angioedema (rare), nausea (common) and pain (frequency unknown) have been added as potential adverse effects of treatment.

Cozaar - Comp (losartan and hydrochlorothiazide) 100/25mg Film-Coated Tablets

SPC updated to note cases of acute respiratory distress syndrome (ARDS) have been reported very rarely after taking hydrochlorothiazide. If ARDS is suspected, treatment with Cozaar-Comp should be withdrawn and appropriate treatment given.

Desloratadine Glenmark 5 mg Tablets

SPC updated with addition of ‘depressed mood’ and ‘eye dried’ as adverse effects of unknown frequency.

Fucidin H (fusidic acid, hydrocortisone acetate) Cream and Fucibet (fusidic acid, betamethasone valerate) Cream

SPC updated to include warning of rebound flares with long term continuous or inappropriate use of topical steroids and addition of withdrawal reactions (redness of the skin, burning or stinging, itch, skin peeling, oozing pustules) as an adverse effect of unknown frequency.

Losec (omeprazole) MUPS Tablets – all strengths

SPC now warns severe cutaneous adverse reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening/fatal, have been reported very rarely and rarely, respectively.

threatening/fatal, have been reported very rarely and rarely, respectively.

Natrilix (indapamide) SR 1.5 mg Tablets

Missing text from warnings section of SPC relating to development of idiosyncratic reaction resulting in choroidal effusion, have been added, to note symptoms include acute onset of decreased visual acuity or ocular pain & typically occur within hours to weeks of drug initiation.

Neurontin (gabapentin) – all presentations

SPC updated with post marketing reports of suicidal ideation and behaviour (frequency not known). The mechanism of this risk is not known. Patients should be monitored and discontinuation of gabapentin treatment should be considered in suspected cases.

Oruvail (ketoprofen) 200 mg Prolonged-Release Hard Capsules

SPC includes warnings on risk of hyperkalaemia with concomitant treatment with potassium salts, potassium-sparing diuretics, ACE inhibitors & ARBs, NSAIDs, heparins, cyclosporine, tacrolimus & trimethoprim. Hyponatraemia & hyperkalemia added as adverse events.

Ovranette 150/30 micrograms Coated Tablets

The wording on angioedema in section 4.8 has been updated in line with PRAC recommendations

Sandimmun and Neoral (ciclosporin) preparations

Increased blood levels of calcineurin inhibitors have been reported with concomitant use of cannabidiol, likely due to P-glycoprotein inhibitory effects of cannabidiol. In transplant patients, trough concentrations should be taken & ciclosporin dose adjusted accordingly.

Sinemet 25 mg/250 mg (carbidopa/ levodopa) Tablets

SPC updated to note that the score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses, and to advise that if a tablet breaks when it is removed from the packaging, it should only be consumed if the whole dose can be taken.

Vagifem (estradiol) 10 micrograms vaginal tablets

SPC updated to note that exogenous oestrogens may induce or exacerbate symptoms of hereditary and acquired angioedema.

Veltassa (Patiromer) 16.8 g powder for oral suspension

Additional mixing options have been added to section 4.2 (posology and method of administration).

Xaggitin (methyphenidate) XL Prolonged-release Tablets – all strengths

Rhabdomyolysis has been added to the SPC as a sign of overdose.

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.