Summary of Product Characteristics updates

Proposed action

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

Action taken

Status | Action due date | Date completed

Accrete D3 (calcium carbonate, colecalciferol) film-coated tablets

SPC updated to note the product has been reclassified from a Prescription Only Medicine (POM) to a Pharmacy (P) medicine.

Asacol (mesalazine) preparations

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been added as a potential adverse effect (frequency unknown). It should be discontinued at first appearance of signs/symptoms of severe skin reactions, eg. rash, mucosal lesions, or other signs of hypersensitivity.

Boots Mouth Ulcer Gel (lidocaine, cetylpyridinium chloride)

SPC updated with requirement of age ≥5 months, new contraindication of current or past history of methemoglobinemia (due to increased risk of methemoglobinemia with overdose in these patients) and warning that this product is not recommended during pregnancy or breastfeeding.

Briviact (brivaracetam) 10 mg/ml oral solution

SPC updated to note brivaracetam is excreted in human milk, and also that limited clinical data are available in neonates (safety information is currently available from 6 neonates).

Femodene (gestodene + ethinylestradiol) tablets

SPC updated to note exogenous oestrogens may induce or exacerbate symptoms of hereditary and acquired angioedema (similar updates have been made to other combined oral contraceptive products).

Flagyl (metronidazole) products

Cases of severe irreversible hepatotoxicity/acute liver failure, including cases with fatal outcomes with very rapid onset after initiation of systemic use of metronidazole, have been reported in patients with Cockayne Syndrome (see section 4.4).

Fragmin (dalteparin) solution for injection- all presentations

Updated with licence extension for treatment of symptomatic VTE in paediatric patients age ≥1 month & statement about 100,000 IU/4ml multidose vial contains benzyl alcohol as preservative, which may cross placenta so Fragmin without preservative should be used during pregnancy.

Jardiance (empagliflozin) 10 mg film-coated tablets

Section 4.4 updated to clarify detail regarding type 1 diabetes (T1D). It should not be used in T1D. Data from a clinical trial showed increased ketoacidosis occurrence (common) in patients treated with empagliflozin as an adjunct to insulin compared to placebo.

Lyrica (pregabalin) hard capsules – all strengths

SPC updated to include drug dependence as a side-effect of unknown frequency.

Nifedipress (nifedipine) preparations

Various changes to the SPC include new contra-indications in women who are or who may become pregnant (previously restricted in pregnancy to use in those with severe hypertension unresponsive to standard therapy), in those with acute porphyria, and in patients with Kock pouch.

Octasa (mesalazine) – all preparations

SPC updated with warning of red-brown urine discolouration after contact with sodium hypochlorite bleach (e.g. from toilets cleaned with such bleaches) and addition of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) as an adverse effect of unknown frequency.

Rapifen (alfentanil)

SPC updated with information on the risk of developing opioid use disorder, and to note the concomitant use of opioids and gabapentinoids increases the risk of opioid overdose, respiratory depression and death.

Repevax (diphtheria, tetanus, pertussis and poliomyelitis) vaccine

New stability data, intended to guide healthcare professionals in case of temporary temperature excursion only, suggest that the vaccine components are stable at temperatures up to 25°C for 72 hours. At the end

of this period, Repevax should be used or discarded.

Salofalk (mesalazine) – all preparations

Updated warnings include: red-brown urine discolouration after contact with sodium hypochlorite bleach, and recommendation to discontinue treatment in event of deterioration of renal function, serious blood dyscrasias, cardiac hypersensitivity and DRESS adverse reactions.

Seroxat (paroxetine)- all presentations

Sections on QT Prolongation (QTP) & implicated drugs have been added. Caution advised in patients with a (family) history of QTP, concomitant use of anti-arrhythmics/other drugs prolonging QT interval, relevant pre-existing cardiac disease, & hypokalaemia/hypomagnesemia.

Tylex (co-codamol 30/500) preparations

SPC now warns of the potential for serotonin syndrome during concomitant use of opioids with serotonergic medicines. Caution is advised, and if serotonin syndrome is suspected, treatment with paracetamol/codeine should be discontinued.

Viagra Connect (sildenafil) 50 mg film-coated tablets

SPC now warns to exercise caution when sildenafil is initiated in patients taking sacubitril/valsartan. Addition of a single dose of sildenafil to sacubitril/valsartan at steady state in patients with hypertension significantly reduced blood pressure vs sacubitril/valsartan alone.

Voltarol (diclofenac sodium) – all presentations

Updated warnings incl risk of oligohydramnios from 20th week of pregnancy therefore use in 1st/2nd trimester is cautioned. Use in 3rd trimester is contraindicated due to cardiopulmonary toxicity, renal dysfunction, prolongation of bleeding, & inhibition of uterine contractions.

Zestoretic 20 (hydrochlorothiazide, lisinopril dihydrate)

SPC now warns very rare cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS) have been reported with hydrochlorothiazide. Symptoms include dyspnoea, fever, pulmonary deterioration & hypotension. If ARDS suspected Zestoretic should be withdrawn.

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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