

Medicines Safety Assurance Tool

January 2022

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Midlands and Lancashire
Commissioning Support Unit

Chloramphenicol eye drops containing borax and boric acid buffers: review of the use in children under 2 years

20 January 2022

Public Assessment Report has been published providing evidence behind recommendation these products can be safely given to infants aged 0 to 2 years as advised by doctor/other prescriber as daily exposure to children would be well below calculated safety limits for most patients.

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

Status	Action due date	Date completed
[Redacted]	[Redacted]	[Redacted]

Summary of Product Characteristics updates

Constella (linaclotide) 290 micrograms hard capsules

SPC updated to warn cases of intestinal perforation reported in patients with conditions that may be linked to localized/diffuse weakness of intestinal wall. Immediate medical care should be sought in case of severe, persistent, or worsening abdo pain and linaclotide stopped.

Cordarone X (amiodarone) 100 mg Tablets

The SPC has been updated with the following adverse effects: neutropenia, agranulocytosis and hallucination (unknown frequency) and decreased libido (common frequency).

Dexasol™ (dexamethasone) 2mg in 5ml solution

A number of changes have been made to the SPC to reflect fact that this version of dexamethasone is now licensed for the treatment of COVID-19 in adolescents (aged 12 years and over) and adults weighing at least 40kg.

Proposed action

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



[Redacted area]

Action taken

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Gardasil 9 suspension for injection

Storage conditions updated to note the finished product is stable for 96 hours when stored at temperatures from 8°C to 40°C or for 72 hours when stored at temperatures from 0°C to 2°C (previously stable for 72 hours when stored at temperatures from 8°C to 25°C or from 0°C to 2°C).

Havrix Junior and non-junior (hepatitis A) Monodose Vaccine

SPC updated to include phenylalanine as an excipient with warning of potential harm to patients that have phenylketonuria.

Keppra (levetiracetam) products

SPC now notes there may be a predisposition to neuroleptic malignant syndrome as an adverse effect of treatment in Japanese patients.

Nebilet (nebivolol) 5mg Tablets

SPC updated to state the effect on human fertility is unknown.

Olmetec plus (olmesartan and hydrochlorothiazide) tablets

SPC notes acute respiratory distress syndrome (ARDS) as a potential adverse effect of treatment (very rare). If ARDS is suspected, treatment should be withdrawn. Hydrochlorothiazide should not be given to patients who have had a previous experience of ARDS.

Pancrex V (pancreatin) Powder

SPC updated with addition of following information: 2 g of Pancrex V Powder corresponds approximately to the volume of a 2.5 ml spoonful and dosing may need to be adjusted, as necessary, on the basis of clinical outcome.

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Pradaxa (dabigatran) 75mg, 110mg and 150 mg hard capsules

Dabigatran is now additionally licensed for the treatment of VTE and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age. Guide discusses the paediatric indication, contraindications, dosing, populations at higher bleeding risk, perioperative management, coagulation tests, overdose, management of complications, special guidance for use of the oral solution, and the patient alert card and counselling.

Prednisolone 25mg Tablets

Hypertrichosis and purpura added as new adverse effects of unknown frequency. Interaction section also updated to advise that prednisolone can lower isoniazid levels by up to 40%.

Pregabalin (Neuraxpharm)

Parkinsonism has been added to the neurological adverse effects associated with this medicine. It is reported as occurring rarely.

Procoralan (ivabradine)

ECG prolonged QT interval and elevated creatinine in blood have been added to SPC as ADRs of uncommon frequency as has information on increased BP observed in SHIFT trial in patients on ivabradine, which was transient, and did not affect treatment effect of ivabradine.

Scopoderm (hyoscine) 1.5 mg Patch

SPC updated to note the patches should only be used with caution in patients with impaired hepatic or renal function; the patches should not be cut, and only one should be applied at one time, and to include detail on how to manage cases of overdose.

Sevikar HCT (olmesartan, medoxomil amlodipine and hydrochlorothiazide) tablets

SPC notes acute respiratory distress syndrome (ARDS) as a potential adverse effect of treatment (very rare). If ARDS is suspected, treatment should be withdrawn. Hydrochlorothiazide should not be given to patients who have had a previous experience of ARDS.

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Suprax (cefixime) 200 mg Tablets

Section 4.4 now notes patients should be informed about the signs and symptoms of serious skin manifestations and monitored closely. Treatment should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of skin hypersensitivity.

Surgam (Tiaprofenic acid) 300 mg Tablets

SPC updated to advise that in common with other NSAIDs, it should not be used during the first two trimesters of pregnancy unless the potential benefit outweighs potential risk, and use in the last trimester is contra-indicated.

Timodine (hydrocortisone, dimeticone, benzalkonium chloride, nystatin) Cream

SPC updated with new indication of hand dermatitis and advice not to use topical corticosteroids for acne vulgaris as they may worsen secondary infected lesions, and not to be used indiscriminately in pruritis. Warning on topical steroid withdrawal syndrome also added.

Warfarin Sodium 1mg/1ml Oral Suspension

SPC updated to note acute kidney injury may occur in patients with altered glomerular integrity or with a history of kidney disease (few cases reported in those with no pre-existing disease). Close monitoring is advised in patients with a supratherapeutic INR and haematuria.

Zoladex LA 10.8mg (goserelin)

This is now licensed for the management of oestrogen-receptor (ER) positive early and advanced breast cancer in pre and peri menopausal women. Various sections of the SPC have been updated with information on its use in this setting.

Zofran (ondansetron) – all presentations

Myocardial ischaemia has been added to SPC as an adverse drug reaction (unknown frequency) from postmarketing experience via spontaneous case reports and literature cases.

Please note that the information in this Safety log is correct at the time of publication. Clinicians should always refer to the most up to date information.

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Zyloric Tablets 100mg (allopurinol)

Aseptic meningitis (frequency unknown) and diarrhoea (uncommon) have been added as side-effects.

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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