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Medicines Safety Assurance Tool February 2018

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MIDLANDS AND LANCASHIRE
COMMISSIONING SUPPORT UNIT

Sodium valproate prescribing data

NHS Business Services Authority | Jan 2018

This report aims to identify the number of female patients of child bearing age that have received prescriptions for sodium valproate. This data will be produced every 6 months to contribute to the monitoring of effectiveness of actions to ensure safe and appropriate use of sodium valproate.

<https://www.nhsbsa.nhs.uk/prescription-data/prescribing-data/sodium-valproate>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Fencino (fentanyl) patches

Electronic Medicines Compendium | 01 Feb 2018

This letter highlights the potential presence of crystals on some patches. They are embedded in the matrix, do not break off by themselves and there is no evidence that the crystals cause skin irritation and there are no patient safety concerns.

<https://www.medicines.org.uk/emc/rmm/1118/Document>

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

Drug interactions with Senna or salbutamol increasing the risk of torsade de pointes

Specialist Pharmacy Service | 05 Feb 2018

This memo for prescribers and pharmacy staff has been produced in response to questions from primary care prescribers and pharmacists concerned about seemingly innocuous drug combinations flagged up on prescribing systems.

<https://www.sps.nhs.uk/memo-drug-interactions-with-senna-or-salbutamol-increasing-the-risk-of-torsade-de-pointes/>

Proposed action

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



[Redacted content]

Action taken

[Redacted content]

Status

Unassigned ▼

Action due date

[Redacted content]

Date completed

[Redacted content]

Changes to Ribena to reduce sugar levels

Royal Pharmaceutical Society | 07 Feb 2018

Lucozade Ribena Suntory are reducing the sugar content of Ribena Blackcurrant (Ready to Drink and squash by approximately 55%). Pharmacists should be aware of this change as Ribena Blackcurrant is sometimes used by people with diabetes to help manage their blood sugar levels.

<https://www.rpharms.com/news/details/Changes-to-Ribena>

Proposed action

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



[Redacted content]

Action taken

[Redacted content]

Status

Unassigned ▼

Action due date

[Redacted content]

Date completed

[Redacted content]

Mycophenolate mofetil, mycophenolic acid: updated contraception advice for male patients

Medicines and Healthcare products Regulatory Agency | 07 Feb 2018

This alert advises that it is now recommended that either the male patient or their female partner use reliable contraception during treatment with mycophenolate medicines and for at least 90 days after stopping.

<https://www.gov.uk/drug-safety-update/mycophenolate-mofetil-mycophenolic-acid-updated-contraception-advice-for-male-patients>

Proposed action

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

[Redacted]

Action taken

[Redacted]

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

Esmya (Ulipristal Acetate) For Uterine Fibroids: Monitor Liver Function In Current And Recent Users; Do Not

Central Alerting System | 09 Feb 2018

This letter is to inform you of temporary safety measures for the medicine Esmya (ulipristal acetate) indicated for pre-operative and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The emergency contraceptive ellaOne also contains ulipristal acetate (single-dose, 30mg). No cases of serious liver injury have been reported with ellaOne and there are no concerns with this medicine at this time.

https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=102937

Proposed action

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

[Redacted]

Action taken

[Redacted]


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

PRAC recommends new measures to avoid valproate exposure in pregnancy

European Medicines Agency | 09 Feb 2018


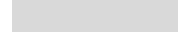
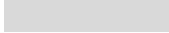
PRAC recommend a new pregnancy prevention programme and inclusion of a visual warning about the risks in pregnancy on the packaging, as well as a patient reminder card for pharmacists to discuss with the patient at the time of dispensing.

http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Valproate_2017_31/Recommendation_provided_by_Pharmacovigilance_Risk_Assessment_Committee/WC500243552.pdf

Proposed action 

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

Action taken


Status: Unassigned  Action due date:  Date completed: 

PRAC recommends updating measures for pregnancy prevention during retinoid use

European Medicines Agency | 09 Feb 2018




PRAC has now updated and harmonised the pregnancy prevention programme for these medicines across the EU.

http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Retinoids_31/Recommendation_provided_by_Pharmacovigilance_Risk_Assessment_Committee/WC500243544.pdf

Proposed action 

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

Action taken

Status: Unassigned  Action due date:  Date completed: 

Ventolin Accuhaler 200mcg and Seretide Accuhaler 50mcg/250mcg

Central Alerting System | 21 Feb 2018

Glaxo Wellcome UK Ltd is recalling two batches of Ventolin Accuhaler and one batch of Seretide 50 microgram / 250 microgram because a manufacturing issue has been identified which has resulted in a small number of units not delivering the full number of doses. Full details of the drug alerts are included in the attached PDF files. Please forward to listed recipients. This information is also published on the MHRA website.

<https://www.gov.uk/drug-device-alerts>

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

Status

Unassigned ▼

Action due date

[Redacted area]

Date completed

[Redacted area]

Summary of Product Characteristics Update

Electronic Medicines Compendium | Feb 2018

Casodex (bicalutamide) Film-coated Tablets

Sections 4.4, 4.5 and 4.8 have been revised to include information about an interaction with coumarin anticoagulants, resulting in increased INR and associated risk of bleeding. Additionally, section 4.6 notes reversible impairment of male fertility in animal studies.

<https://www.medicines.org.uk/emc/product/5491/smpc>

CellCept (mycophenolate mofetil) capsules, tablets, powder for oral suspension and powder for concentrate for solution for infusion

Electronic Medicines compendium

Cardiovascular system disorders | Liver disorders | Renal and urologic disorders | Surgery

Section 4.4 advises therapeutic drug monitoring of mycophenolic acid may be appropriate when switching combination therapy (e.g. from ciclosporin to tacrolimus or vice versa) or to ensure adequate immunosuppression in patients with high immunological risk (e.g. risk of rejection).

<https://www.medicines.org.uk/emc/product/1569/smpc>

Concerta XL (methylphenidate) prolonged-release Tablets

Section 4.8 advises that aggression, anxiety, agitation and tension have been reported in patients taking methylphenidate.

<https://www.medicines.org.uk/emc/product/6872/smpc>

Curaderm Ointment (tacalcitol monohydrate)

SPC now warns butylhydroxytoluene (E 321) contained in the excipient white soft paraffin, may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

<https://www.medicines.org.uk/emc/product/6389/smpc>

Epanutin (phenytoin) – all strengths and formulations

Section 4.5 has been revised to include an interaction with disopyramide. Furthermore, a statement advising that the lists of interacting drugs in section 4.5 are not intended to be all-inclusive, and individual product information should also be consulted.

<https://www.medicines.org.uk/emc/product/2257/smpc>

Proposed action

Newsletter

Optimise Rx/ScriptSwitch

Practice audit/search

Other (please specify)

Action taken

Status

Unassigned ▼

Action due date

Date completed

Gilenya (fingolimod) 0.5mg hard capsules

Section 4.4 advises that rebound disease activity has been observed in the post-marketing setting in some patients stopping fingolimod. If discontinuation of fingolimod is deemed necessary, patients should be monitored during this time for relevant signs of a possible rebound.

<https://www.medicines.org.uk/emc/product/4545/smpc>

Iclusig (ponatinib) tablets

Severe skin reactions (such as Stevens - Johnson syndrome) have been reported in the post-marketing setting. Patients to immediately report suspected skin reactions, especially with blistering, peeling, mucosal involvement or systemic symptoms.

<https://www.medicines.org.uk/emc/product/8653/smpc>

Imbruvica (ibrutinib) capsules

Panniculitis (inflammation of adipose tissue) has been added as an uncommon potential adverse effect from treatment.

<https://www.medicines.org.uk/emc/product/3414/smpc>

INFANRIX-IPV+Hib powder and suspension for suspension for injection

Section 2 now states that that the vaccine may contain traces of neomycin, polymyxin and polysorbate 80 which are used during the manufacturing process, and cross-refers to section 4.3 to contra-indicate use in people with hypersensitivity to these.

<https://www.medicines.org.uk/emc/product/5301/smpc>

Kivexa film-coated tablets (600 mg abacavir and 300 mg lamivudine)

SPC now advises that chronic co-administration of Kivexa with medicinal products containing sorbitol/other osmotic acting poly-alcohols or monosaccharide alcohols should be avoided. More frequent monitoring of HIV-1 viral load is suggested when this cannot be avoided.

<https://www.medicines.org.uk/emc/product/3881/smpc>

Klaricid (clarithromycin)- various strengths and preparations

SPC updated with adverse effect of severe cutaneous adverse reactions e.g. acute generalised exanthematous pustulosis (unknown frequency).

<https://www.medicines.org.uk/emc/product/8600/smpc>

Lariam (mefloquine) 250mg Tablets

Sections 4.4 and 4.8 now include insomnia as an adverse effect associated with mefloquine.

<https://www.medicines.org.uk/emc/product/1108/smpc>

Loceryl Curanail 5% w/v Medicated Nail Lacquer

SPC now advises that cosmetic nail lacquer may be applied at least 10 min after amorolfine; and before repeat application of amorolfine, any remaining lacquer should be removed carefully, and affected nails filed down again as required.

<https://www.medicines.org.uk/emc/product/192/smpc>

Maxtrex (methotrexate) Tablets (all strengths)

Concomitant administration of levetiracetam and methotrexate (MTX) has been reported to decrease MTX clearance, resulting in increased/prolonged blood concentration to potentially toxic levels. Levels of both should be carefully monitored in patients treated concomitantly.

<https://www.medicines.org.uk/emc/product/1376/smpc>

Mysimba (8 mg naltrexone /90 mg bupropion) prolonged-release tablets

Contraindication for severe renal impairment has been removed; posology, special warnings and precautions for use, side effects and pharmacokinetic sections have been updated for patients with renal impairment.

<https://www.medicines.org.uk/emc/product/2684/smpc>

<https://www.medicines.org.uk/emc/product/2697/smpc>

Noriday (progesterone) tablets

SPC now highlights that in very rare cases hepatic adenomas may be associated with progesterone-only pill use. Also, in extremely rare cases, hepatocellular carcinoma may be associated with combined oral contraceptives use.

<https://www.medicines.org.uk/emc/product/1146/smpc>

Olysio (simeprevir) 150mg hard capsules

The section in SPC on photosensitivity reactions linked to use in combination treatment in the post-marketing setting has been amended to state that some of these reactions have resulted in hospitalisation.

<https://www.medicines.org.uk/emc/product/5390/smpc>

Pradaxa (dabigatran) hard capsules

A new section on discontinuation of dabigatran has been added to SPC, advising that treatment should not be discontinued without medical advice. Patients should be instructed to contact treating clinician if they develop GI symptoms such as dyspepsia.

<https://www.medicines.org.uk/emc/product/6228/smpc>

Rifadin (Rifampicin) Capsules and Oral Suspension

Section 4.4 now warns rifampicin may produce a discoloration (yellow, orange, red, and brown) of the teeth, urine, sweat, sputum and tears, and the patient should be forewarned of this. Additionally, soft contact lenses have been permanently stained (section 4.8).

<https://www.medicines.org.uk/emc/product/6383/smpc>

Rifinah (isoniazid/rifampicin) tablets

Section 4.4 now warns rifampicin may produce a discoloration (yellow, orange, red, and brown) of the teeth, urine, sweat, sputum and tears, and the patient should be forewarned of this. Soft contact lenses have been permanently stained (sec. 4.8).

<https://www.medicines.org.uk/emc/product/6123/smpc>

Selincro (nalmefene) 18mg film-coated tablets

SPC now states that increased suicidal risk in alcohol and substances abusers, with or without accompanying depression, is not reduced by the intake of nalmefene. Myalgia has been added as undesirable effect of unknown frequency.

<https://www.medicines.org.uk/emc/product/3051/smpc>

Seretide (salmeterol/fluticasone) products

PRAC recommendations for interaction of corticosteroids with cobicistat-containing products have been incorporated into SPC. Pregnancy/lactation and clinical studies sections of SPC have been revised based upon new epidemiology data. Paediatric study data have been added to SPC.

<https://www.medicines.org.uk/emc/product/5504/smpc>

Sevodyne (buprenorphine) 20microgram/hour transdermal patch

Section 4.6 has been amended to note that prolonged use of buprenorphine during pregnancy can result in neonatal opioid withdrawal syndrome. Aggression, urinary incontinence and urinary hesitation have been added to the uncommon side effects.

<https://www.medicines.org.uk/emc/product/7372/smpc>

Taptiqom (tafluprost 15 micrograms/ml + timolol 5 mg/ml) eye drops, solution in single-dose container

SPC now warns that there is a potential for hair growth to occur in areas where tafluprost solution comes repeatedly in contact with the skin surface. Macular oedema/cystoid macular oedema has been added as ADRs to SPC.

<https://www.medicines.org.uk/emc/product/6917/smpc>

Tildiem (Diltiazem) Modified-Release Tablets

SPC now details that diltiazem may induce bronchospasm, including asthma aggravation, especially in patients with pre-existing bronchial hyper-reactivity. Cases have also been reported after dose increase. Patients should be monitored for signs of respiratory impairment.

<https://www.medicines.org.uk/emc/product/1465/smpc>

Tritace (ramipril) tablets

Concomitant use of ACE inhibitors with sacubitril/valsartan (SV) is now contraindicated as this increases angioedema risk. Treatment with ramipril (RM) must not be started until 36 hours after taking last dose of SV; and SV must not be started until 36 hours after last dose of RM.

<https://www.medicines.org.uk/emc/product/2760/smpc>

Trizivir (abacavir, lamivudine and zidovudine) film-coated tablets

SPC updated to recommend chronic co-administration with medicinal products containing sorbitol or other osmotic acting poly-alcohols or monosaccharide alcohols be avoided where possible. If necessary then more frequent HIV-1 viral load monitoring should be considered.

<https://www.medicines.org.uk/emc/product/1307/smhc>

Truvada (emtricitabine/tenofovir) film-coated tablets

SPC has been updated to extend the indication for use of pre-exposure prophylaxis in adolescents aged 12 years and older, weighing at least 35Kg.

<https://www.medicines.org.uk/emc/product/3890/smhc>

Utovlan (Norethisterone) Tablets

Information has been added to the SPC on the association of hepatic adenoma with the use of the progesterone only pill.

<https://www.medicines.org.uk/emc/product/1717/smhc>

Vibramycin-D (doxycycline) dispersible tablets 100mg

The entire SPC has been updated to provide further information about reversible tooth discoloration with doxycycline. Section 4.2 now states Vibramycin is contraindicated in children under the ages of 12 years.

<https://www.medicines.org.uk/emc/product/6262/smhc>

Xalacom (latanoprost with timolol maleate) eye drops, solution

Section 4.8 now includes the following adverse effects associated with Xalacom: angina, eyelid oedema, localized skin reaction on the eyelids and pseudopemphigoid of the ocular conjunctiva.

<https://www.medicines.org.uk/emc/product/1536/smhc>

Zeffix (lamivudine) and lamivudine continuing products (Triumeque, Combivir)

The SPC advises to avoid chronic co-administration of lamivudine with medicinal products containing sorbitol or other osmotic acting poly-alcohols or monosaccharide alcohols (e.g. xylitol, mannitol, lactitol, maltitol). If unavoidable, more frequent monitoring of HBV viral load is suggested when this cannot be avoided.

<https://www.medicines.org.uk/emc/product/3834/smhc>

Zelboraf (vemurafenib)240mg Film Coated Tablets

Sections 4.4 and 4.5 include revised information about concomitant use with drugs metabolised by CYP1A2 and CYP3A4 with narrow therapeutic windows, and medicines which are P-glycoprotein substrates. Section 4.6 advises vemurafenib could cause fetal harm in pregnant women.

<https://www.medicines.org.uk/emc/product/3948/smpc>

Zocor (simvastatin) Film-coated tablets (all strengths)

Section 4.5 now advises to consult the prescribing information of all concomitantly used drugs to obtain further information about potential interactions with simvastatin and/or potential enzyme or transporter alterations and possible adjustments to dose and regimen.

<https://www.medicines.org.uk/emc/product/7787/smpc>

statusOptions

Unassigned

Red

Amber

Green