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## Medicines Safety Assurance Tool Feb-19

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](mailto:mlcsu.medicines-safety@nhs.net)



Midlands and Lancashire  
Commissioning Support Unit

### Carbimazole - increased risk of congenital malformations; strengthened advice on contraception

*Medicines and Healthcare products Regulatory Agency | 18 February 2019*

Carbimazole is associated with increased risk of congenital malformations when used during pregnancy, particularly in first trimester and at high doses (>15mg carbimazole daily). Women of childbearing potential should use effective contraception during treatment with carbimazole.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/779462/DSU-PDF-Feb-2019.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779462/DSU-PDF-Feb-2019.pdf)

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

### Carbimazole and risk of acute pancreatitis

*Medicines and Healthcare products Regulatory Agency | 18 February 2019*

This Safety Update alerts that cases of acute pancreatitis have been reported very infrequently during treatment with carbimazole; if acute pancreatitis occurs, treatment should be discontinued immediately. Re-exposure may result in life-threatening acute pancreatitis.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/779462/DSU-PDF-Feb-2019.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779462/DSU-PDF-Feb-2019.pdf)

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

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### SGLT2 inhibitors and reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum)

Medicines and Healthcare products Regulatory Agency | 18 February 2019

The safety alert states if Fournier's gangrene is suspected, stop the SGLT2 inhibitor and start treatment urgently. Patients should be advised to seek urgent medical attention if they experience severe pain, tenderness, erythema, or swelling in genital or perineal area, accompanied by fever or malaise.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/779462/DSU-PDF-Feb-2019.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779462/DSU-PDF-Feb-2019.pdf)

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

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### Royal Pharmaceutical Society issues warning about DNP (2,4-dinitrophenol) in products used for weight loss weight loss

Royal Pharmaceutical Society | 27 February 2019

The warning advises DNP is an industrial chemical used in pesticides and explosives and is unfit for human consumption but sold illegally via the internet for weight loss. It acts as a 'fat burner' by raising metabolism and has contributed to a significant number of deaths.

<https://www.rpharms.com/about-us/news/details/Deadly-diet-drug-DNP-can-kill>

Proposed action

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



Action taken

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Unassigned ▼

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## Summary of Product Characteristics Update

Electronic Medicines Compendium | February 2019

### Advagraf (tacrolimus) prolonged-release hard capsules (all strengths)

In section 4.5 an additional paragraph describing the effect of switching ciclosporin to tacrolimus and its effect on mycophenolic acid exposure has been added. Section 4.8 now includes thrombotic microangiopathy, and optic neuropathy as adverse effects.

<https://www.medicines.org.uk/emc/product/7526/smpc>

### Ativan injection (lorazepam)

Sections 4.2 and 4.4 of have been updated with information regarding a risk of falls in the elderly.

<https://www.medicines.org.uk/emc/product/5473/smpc>

### Cardura (doxazosin) tablets

The SPC now reflects that doxazosin is a substrate of cytochrome P450 3A4 (CYP 3A4) and that caution should be exercised when concomitantly administering doxazosin with a strong CYP 3A4 inhibitor (e.g. clarithromycin, itraconazole, ritonavir, voriconazole).

<https://www.medicines.org.uk/emc/product/1064/smpc>

### Cerazette (desogestrel) 75 microgram film-coated tablet

Section 4.4 of the SPC advises that depressed mood and depression are well known side effects of hormone contraceptive use, stating it can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women are advised to contact their physician in case of mood changes.

<https://www.medicines.org.uk/emc/product/1698/smpc>

### Coversyl Arginine (perindopril arginine)

Raynaud's Phenomenon has been added as adverse effect of unknown frequency to SPC.

<https://www.medicines.org.uk/emc/product/6224/smpc>

### Inhixa (enoxaparin biosimilar) solution for injection

The SPC has been updated to reflect that Inhixa is now available as two strengths - 12,000 IU (120mg) and 15,000 IU (150mg) solution for injection.

<https://www.medicines.org.uk/emc/product/9854/smpc>

Proposed action

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



Action taken

Status

Unassigned



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**Lopid (gemfibrozil) 600 mg film-coated tablet**

SPC updated to include addition of enzalutamide to the existing list of drugs that are CYP2C8 substrates which can interact with gemfibrozil; and addition of information that co-administration of gemfibrozil with enzalutamide may increase the risk of seizures.

<https://www.medicines.org.uk/emc/product/132/smpc>

**Maxitrol (dexamethasone/polymyxin B sulphate/neomycin sulphate) Ointment**

The SPC has been updated with new contraindication of untreated parasitic eye infections and Stevens-Johnson syndrome has been added as ADR (unknown frequency). It now also states that severity of hypersensitivity reactions may vary from local effects to generalized reactions.

<https://www.medicines.org.uk/emc/product/842/smpc>

**Modigraf (tacrolimus) granules for oral suspension (all strengths)**

Section 4.4 of the SPC now advises increased risk of infections with viral hepatitis. Section 4.5 now describes the effect of switching ciclosporin to tacrolimus and its effect on mycophenolic acid exposure. Section 4.8 includes thrombotic microangiopathy, and optic neuropathy as adverse effects.

<https://www.medicines.org.uk/emc/product/461/smpc>

**Natrilix (Indapamide) 2.5 mg Tablets and Natrilix (Indapamide) SR 1.5 mg Tablets**

The SPC has been updated to add an interaction with allopurinol, whereby concomitant treatment with indapamide may increase the incidence of hypersensitivity reactions to allopurinol.

<https://www.medicines.org.uk/emc/product/1151/smpc>

**Rifampicin containing products (Rifinah, Rifater, Rifadin)**

SPCs updated to warn rifampicin may cause vitamin K dependent coagulopathy and severe bleeding. Monitoring of occurrence of coagulopathy is recommended for patients at particular bleeding risk.

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

**Rifater (isoniazid, rifampicin, pyrazinamide) and Rifanah (isoniazid, rifampicin) tablets**

The SPC advises on drug interactions with progestogens and riluzole. Plasma concentrations of morphine may also be reduced by rifampicin. The analgesic effect of morphine should be monitored, and dosing adjusted during and after treatment with rifampicin.

<https://www.medicines.org.uk/emc/product/1596/smpc>

**Rifinah 300mg/150mg (rifampicin/isoniazid) Tablets**

The SPC now warns that plasma concentrations of morphine may be reduced by rifampicin, therefore analgesic effect should be monitored, and doses of morphine adjusted during and after treatment with rifampicin.

<https://www.medicines.org.uk/emc/product/6124/smpc>

**Tacrolimus (Advagraf, Prograf, Modigraf brands) -various preparations**

The SPC now includes viral hepatitis as a potential opportunistic infection that patients taking immunosuppressants, including tacrolimus, may be at increased risk of developing.

<https://www.medicines.org.uk/emc/product/7526/smpc>

**Truberzi (eluxadoline) film-coated tablets – all strengths**

Section 4.5 of the SPC has been updated to include information about the potential for mild induction of CYP3A4; Systemic exposure to medicinal products metabolised by CYP3A4 may be decreased when co-administered with eluxadoline.

<https://www.medicines.org.uk/emc/product/2503/smpc>

**Zirtek (cetirizine) preparations**

Nightmares (very rare), arthralgia (frequency unknown) and acute generalised exanthematous pustulosis (very rare) are now listed as potential adverse effects of treatment on the SPC.

<https://www.medicines.org.uk/emc/product/6752/smpc>