



MHRA Drug Safety Update

Link to February 2019 Drug Safety Update, [Carbimazole: increased risk of congenital malformations; strengthened advice on contraception](#) and [Carbimazole: risk of acute pancreatitis](#) added to carbimazole entry in TAF.

Link to [FSRH statement on contraception for women using known or potential teratogenic drugs](#) (February 2018) added to carbimazole entry in TAF.

Link to February 2019 Drug Safety Update, [SGLT2 inhibitors: reports of Fournier's gangrene \(necrotising fasciitis of the genitalia or perineum\)](#) added to individual SGLT2 inhibitors and SGLT2 inhibitor/combination product entries in TAF (including non formulary entries)



SMC Advice

Published 11th February 2019

Dabrafenib 50mg and 75mg hard capsules (Tafinlar®) SMC2131

Eslicarbazepine acetate 200mg and 800mg tablets and oral suspension 50mg/mL (Zebinix®) SMC2087

Rivaroxaban 2.5mg film-coated tablet (Xarelto®) SMC2128

Romiplostim 125 micrograms, 250 micrograms, 500 micrograms powder for solution for injection (Nplate®) SMC2126

Tisagenlecleucel $1.2 \times 10^6 - 6 \times 10^8$ cells dispersion for infusion (Kymriah®) SMC2129

Tofacitinib 5mg, 10mg film-coated tablets (Xeljanz®) SMC2122

...continued on back page

Cardiology Formulary Review

[Chapter 2 \(Cardiovascular system\)](#) of the formulary has been reviewed in relation to [SIGN 151 Management of stable angina, April 2018](#) and [SIGN 152 Cardiac arrhythmias in coronary heart disease, September 2018](#).

Notable changes made to the formulary include:

- Flowchart for sequence of drug treatment for stable angina is currently being updated so that for initiation of treatment, beta blockers are listed as first-line for the relief of symptoms of stable angina. For initiation of treatment, calcium channel blockers (rate-limiting or dihydropyridine depending on contraindications and co-

morbidity) are listed as second-line where beta blockers are contra-indicated.

- Advice added to formulary [section 02.09 Antiplatelet drugs](#) to refer to individual patient recommendations from Cardiology on anticoagulant or antiplatelet treatment from the patient's record on Clinical Portal for any patients having undergone percutaneous coronary intervention (PCI).
- Magnesium sulphate injection for management of cardiac arrhythmias added to [Cardiology specialist formulary list](#) and magnesium sulphate injection formulary entry (Hospital Only - Red traffic light).

Once Daily Tadalafil

- Tadalafil once daily (Amber traffic light in formulary) is now restricted for initiation in Tayside to use only for erectile dysfunction after radical pelvic surgery in those who do not tolerate or achieve an adequate response with sildenafil. Tadalafil once daily is now non-formulary for all other indications.
- Sildenafil is now the first choice in Tayside for erectile dysfunction after radical pelvic surgery (Amber traffic light in formulary).
- These treatments may be prescribed by GPs on the advice of a Urology specialist.
- Local treatment protocols for [sildenafil](#) and [tadalafil](#) (accessible with Staffnet intranet access) for erectile dysfunction after radical pelvic surgery (including radical prostatectomy) which outline recommended doses and treatment duration are now available.

Medicines Information on the Knowledge Network

The majority of Medicines Information resources on the Knowledge Network are available to access under the 'Medicines Information Resources' tab in 'More Information Sources' section from the home page of the [Knowledge Network](#).

Resources available include:

Medicines Complete Package
BNF and BNF for children (BNFC), Martindale: The Complete Drug Reference, Handbook of Drug Administration via Enteral Feeding Tubes (revised 3rd edition, 2018), Herbal Medicines, Palliative Care Formulary, Stockley's Drug Interactions, Stockley's Interaction Checker and Martindale ADR Checker.

Other Useful Resources

Drugs during Pregnancy & Lactation: Treatment Options (Schaefer) and Drugs

in Pregnancy & Lactation: a Reference Guide (Briggs), Micromedex, Renal Drug Database (username & password available via ann.lees@nes.scot.nhs.uk), BMJ Best Practice and Specialist Pharmacy Services website.

The majority of resources will log you in automatically from an NHS computer. If this is not the case or you are working from a non-NHS computer log in via Shibboleth/ Open Athens at the top right hand side. If you do not have or cannot remember your Open Athens username (begins with efsxxxxx) click on register button to register or obtain forgotten password.

Further guidance available from
TAY-UHB.medinfo@nhs.net

For full information on any of the drugs listed below use the link to the Scottish Medicines Consortium (SMC) website below to search by generic, brand or SMC no.

See NHS Tayside 'Local Decisions on SMC Advice' database (link below) for full details on Board decisions - these are currently listed alphabetically by page.

SMC Advice continued

SMC 'Not recommended' medicines - February 2019

Axicabtagene ciloleucel 0.4 – 2 x 10⁸ cells dispersion for infusion dispersion for infusion (Yescarta®) SMC 2114

Cabozantinib 20mg, 40mg and 60mg tablets (Cabometyx®) SMC2160

Cabozantinib 20mg, 40mg, and 60mg film-coated tablets (Cabometyx®) SMC2136

Dexmedetomidine 100 micrograms/ml concentrate for solution for infusion (Dexdor®) SMC 2161

Doravirine 100mg / lamivudine 300mg/tenofovir disoproxil 245mg film-coated tablets (Delstrigo®) SMC 2163

Doravirine 100mg film-coated tablets (Pifeltro®) SMC 2162

Pembrolizumab 25mg/mL concentrate for solution for infusion and 50mg powder for concentrate for solution for infusion (Keytruda®) SMC2127

Published 11th March 2019

Letermovir 240mg film-coated tablets (Prevymis®) SMC1338/18

Liposomal formulation of daunorubicin/cytarabine 44mg/100mg powder for concentrate for solution for infusion (Vyxeos®) SMC2130

SMC 'Not recommended' medicines - March 2019

Epoetin alfa 2,000 / 4,000 / 10,000 / 40,000 international units per mL solution for injection in pre-filled syringe (Eprex®) SMC2164

Rituximab 100mg, 500mg solution for infusion (MabThera®) SMC2165

Tisagenlecleucel 1.2 x 10⁶ to 6 x 10⁸ cells dispersion for infusion (Kymriah®) SMC2141

Published 8th April 2019

Blinatumomab 38.5 micrograms powder for concentrate and solution for infusion (Blincyto®) SMC2148

Certolizumab pegol 200mg solution for injection in pre-filled syringe and pen (Cimzia®) SMC2132

Dasatinib 20mg, 50mg, 80mg, 100mg, 140 mg film-coated tablets (Sprycel®) SMC2142

Erenumab 70mg solution for injection in pre-filled pen (Aimovig®) SMC2134

Lenvatinib 4mg hard capsules (Lenvima®) SMC2138

Mepolizumab 100mg powder for solution for injection (Nucala®) SMC2139

Rufinamide 40mg/mL oral suspension and 100mg, 200mg, 400mg tablets (Inovelon®) SMC2146

Testosterone 20mg/g transdermal gel (Testavan®) SMC2152

Medicines within the Tayside Area Formulary are intended to guide choice on a rational selection of medicines for **adults** which have been included on the basis of clinical efficacy, safety, patient acceptability and cost-effectiveness.

This bulletin is produced by the Medicines Advisory Group (MAG), which is a sub-group of the NHS Tayside Area Drug and Therapeutics Committee. Please direct any queries to:

Hazel Steele, Lead Pharmacist, Prescribing Support
E-mail: hazelsteele@nhs.net

Claire James, Senior Pharmacist - Clinical Effectiveness
E-mail: clairejames@nhs.net

Karen Harkness, Principal Pharmacist, Clinical Effectiveness
E-mail: kharkness@nhs.net

New & Updated Formulary Links

- [Tayside Prescriber 155 - Re-classification of pregabalin and gabapentin](#)
- [RC PSYCH PS04/18: Withdrawal of, and alternatives to, valproate-containing medicines in girls and women of childbearing potential who have a psychiatric illness](#)
- [MHRA Drug Safety Update, January 2019. Tapentadol \(Palexia\): risk of seizures and reports of serotonin syndrome when co-administered with other medicines](#)

Other Formulary Updates

- Baricitinib (Olumiant® ▼) added to formulary (Red traffic light) restricted to use in severe rheumatoid arthritis (DAS 28 score >5.1) (monotherapy or with methotrexate) in patients who have not responded to intensive therapy with a combination of conventional DMARDs or in patients with severe disease inadequately controlled by a TNF antagonist.
- Trimovate® cream (clobetasone butyrate 0.05% with nystatin and oxytetracycline) added as Amber traffic light to [Dermatology specialist formulary list](#) restricted to use for patients with complex skin conditions requiring secondary care referral and who may otherwise require systemic antibiotics.
- Levosert® (intra-uterine system containing levonorgestrel 52mg) added as Green traffic light restricted to use as alternative to Mirena® (intra-uterine system containing levonorgestrel 52mg) for contraception and/or heavy menstrual bleeding (after the exclusion of any pathology) in women under the age of 45 who are unlikely to require HRT in the near future, and whose cervix and uterus is easily sounded (without obvious cervical stenosis etc) or when the inserting health care provider is confident in performing cervical dilatations and blocks.
- NiQuitin® minis lozenges (mint) 1.5mg & 4mg replaced with Nicotinell® lozenges (mint) 1mg, 2mg.

Links to Additional Information

Monthly Drug Safety Updates:

www.gov.uk/government/publications/drug-safety-update-monthly-newsletter

For full details of medicines and forthcoming SMC Advice see **SMC Website:**

www.scottishmedicines.org.uk

For a Summary of a Product's Characteristics (SPCs) see **Electronic Medicines Compendium Website:**

<http://www.medicines.org.uk/emc/>

For full details on NHS Board decisions see **Tayside Area Formulary - Local Decisions on SMC Advice database:**

<http://www.nhstaysideadtc.scot.nhs.uk/approved/formular/NewMedsHomepage.htm>

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the [Policy on Prescribing of Non-Formulary Medicines \(including PACS Tier 1 & 2\)](#)

Local implementation of SMC recommendations is taken forward by the Tayside Prescribing Support Unit (PSU). This bulletin is based on evidence available to the Tayside Prescribing Support Unit at time of publication and is covered by the [NHS Tayside Privacy and Accessibility Statements](#).