



Ingenol mebutate (Picato®) gel and risk of skin cancer

The European Medicines Agency (EMA) safety committee (Pharmacovigilance Risk Assessment Committee (PRAC)) has started a review of data on skin cancer in patients using Picato®, a gel for treating actinic keratosis. The review was triggered by data from several studies showing a higher number of skin cancer cases, including cases of squamous cell carcinoma, in patients using Picato®.

Healthcare professionals are advised to use Picato® with caution in patients who have had skin cancer in the past. In addition, patients should continue to watch out for any skin lesions and inform their doctor immediately if they notice anything unusual. Patients who have questions or concerns about their treatment should contact their doctor.



Due to safety concerns and the fact that there are several alternative formulary preparations for actinic keratosis, Picato® gel has been removed from the [Tayside Area Formulary](#) until the outcome of the review.

Please see [EMA review on Picato®, September 2019](#) for further information.

Febuxostat in patients with a history of cardiovascular disease

Febuxostat should be avoided in patients with pre-existing major cardiovascular disease (e.g. MI, stroke or unstable angina) unless no other therapy options are appropriate.

Current guidance for gout recommends treatment with febuxostat only when allopurinol is not tolerated or contraindicated. Suspected adverse drug reactions to febuxostat should be reported on a [Yellow Card](#). See [July's Drug Safety Update](#) for further information.

Letters have gone out to GPs in Tayside who have patients on the FAST study (febuxostat versus allopurinol streamlined trial comparing cardiovascular safety of allopurinol & febuxostat).

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>

Rivaroxaban (Xarelto ▼) 15mg and 20mg tablets

[July's Drug Safety Update](#) reminds us of the importance of taking rivaroxaban 15mg and 20mg tablets **with food**. A small number of reports of thromboembolic events have been reported to the MHRA which may have been due to the patient taking the tablets on an empty stomach.

The bioavailability of a 15mg & 20mg dose is reduced to about 66% in the fasting state compared to almost complete absorption and high bioavailability if taken with food.

The bioavailability of 2.5mg and 10mg rivaroxaban tablets are not affected by food.

Any suspected adverse reactions, including suspected events associated with lack of efficacy to rivaroxaban should be reported on a [Yellow Card](#).



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:

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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

Published 8 July 2019

Arsenic trioxide 1mg/mL concentrate for solution for infusion (Trisenox®) SMC2181

Daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) SMC2180

Palbociclib 75mg, 100mg, and 125mg hard capsules (Ibrance®) SMC2149

SMC 'Not recommended' medicines - July 2019

Benralizumab 30mg solution for injection in pre filled syringe (Fasenra®) SMC2155

Darvadstrocel 30 million cells/6mL suspension for injection (Alofisel®) SMC2115

Encorafenib 50mg and 75mg hard capsules (Braftovi®) SMC2145

Nivolumab 10mg/mL concentrate for solution for dilution (Opdivo®) SMC2153

Published 12 August 2019

Buprenorphine 8/16/24/32/64/96/128 mg prolonged-release solution for injection (Buvidal®) SMC2169

Empagliflozin plus linagliptin 10mg/5mg, 25mg/5mg film-coated tablets (Glyxambi®) SMC1236/17

Inotersen 284mg solution for injection in pre-filled syringe (Tegsedi®) SMC2188

Perampanel 0.5mg/mL oral suspension (Fycompa®) SMC2172

Tildrakizumab 100mg solution for injection in pre-filled syringe (Ilumetri®) SMC2167

Venetoclax 10mg, 50mg, and 100mg film-coated tablets (Venclyxto®) SMC2166

SMC 'Not recommended' medicines - August 2019

Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg hard capsules (Revlimid®) SMC2217

Lumacaftor and ivacaftor 200mg/125mg, 100mg/125mg film-coated tablets and 100mg/125mg, 150mg/188mg granules in sachets (Orkambi®) SMC2182

Perampanel 0.5mg/mL oral suspension (Fycompa®) SMC2218

Pomalidomide 1mg, 2mg, 3mg and 4mg hard capsules (Imnovid®) SMC2219

Rucaparib 200mg, 250mg and 300mg film-coated tablets (Rubraca®) SMC2221

Tezacaftor and ivacaftor 100mg/150mg film-coated tablets (Symkevi®) SMC2183

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](#).

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 \(including PACS Tier 1 & 2\)](#)

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.

New & Updated Formulary Links

- [Pill in the pocket flecainide guidance](#)
- [Magnesium sulphate: risk of skeletal adverse effects in the neonate following prolonged or repeated use in pregnancy. Drug Safety Update volume 12, issue 10: May 2019: 3](#)
- [Oral retinoid medicines ▼: revised and simplified pregnancy prevention educational materials for healthcare professionals and women. Drug Safety Update volume 12, issue 11: June 2019: 4](#)
- [NHS Tayside Respiratory MCN Guidance on Respiratory use of long term azithromycin in adults](#)
- [Latest supply status of EpiPen® 150mcg and 300mcg adrenaline auto injectors](#)
- [GLP-1 receptor antagonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued. Drug Safety Update volume 12, issue 11: June 2019: 2](#)
- [Algorithm for Treatment of Overactive Bladder \(OAB\) in Primary Care](#)
- [NICE NG123 Urinary incontinence and pelvic organ prolapse in women: management, April 2019](#)
- [GP, Community Nurse and Specialist Nurse Oral Nutritional Supplement \(ONS\) Formulary for Adults](#)
- [GP, Community Nurse and Specialist Nurse Oral Nutritional Supplement Prescribing Guidelines for Adults](#)

Other Formulary Updates

- Rasagiline added to formulary (Amber traffic light) as 1st choice MAO-B inhibitor for Parkinson's disease, selegiline now 2nd choice.
- Solifenacin changed from Amber to Green traffic light and now 2nd choice urinary antimuscarinic (after tolterodine). Oxybutynin changed from Green to Amber traffic light for Treatment of overactive bladder (OAB) in adults - initiation on the advice of Urology/Uro-gynaecology. Further detail on recommendations for blood pressure monitoring added for mirabegron. Now specifies blood pressure should be measured before starting, one month after initiation, and at least annually.
- Tocilizumab (RoActemra®) in Rheumatology - indication added to formulary: FIRST CHOICE biologic agent for giant cell arteritis (GCA) in patients with newly diagnosed GCA or relapsed disease - treatment subject to 12 month clinical stopping rule.
- Memantine – information added to formulary entry that the treatment initiation pack (7x5mg, 7x10mg, 7x15mg, 7x20mg tablets) should only be prescribed when necessary as it is significantly more expensive than use of the 10mg tablets which can be halved.