



Miconazole (Daktarin®) - Over-The-Counter Oral Gel

Due to safety issues and continued reports of increased INR with warfarin and miconazole, miconazole oral gel (pharmacy (P) medicine) can no longer be sold by a community pharmacy to anyone who is prescribed warfarin.

This contraindication will be clearly highlighted on the outer carton and tube of the pharmacy (P) medicine.

Miconazole oral gel can still be prescribed to a patient on warfarin as long as INR is carefully monitored. However, nystatin is preferred in patients on warfarin.

See [September's Drug Safety Update](#) for more detail.

Protocol Update

Melatonin 2mg modified release tablets are the 1st choice formulation for chronic sleep disorders in children in NHS Tayside. They are more cost effective than Bio-melatonin® 3 mg tablets which are unlicensed. Patients on Bio-melatonin® are currently being switched to the 2mg modified release tablets.

The [melatonin protocol](#) has been updated to reflect this change. Of note melatonin should not routinely be used for prolonged periods.

Loperamide (Imodium®): Reports of Serious Cardiac Events in Overdose

Loperamide, an opioid receptor agonist, has low systemic bioavailability (0.3%) due to extensive 1st pass metabolism and is considered very safe at licensed therapeutic doses. Loperamide is available on general sale (GSL) for example via supermarkets, as a pharmacy (P) medicine and as a prescription only medicine (POM). There have been reports of QT prolongation, torsades de pointes and cardiac arrest in patients who have overdosed with loperamide (doses from 40mg up to 800mg daily). The SPCs and PILs for loperamide are being updated to include warnings of cardiac events with high dose of loperamide and to warn patients not to exceed the recommended amount (maximum daily dose 16mg). See [September's Drug Safety Update](#) for more detail.

Formulary Review: Hormone Replacement Therapy (HRT)

Sections [06.04.01](#) & [07.02.01](#) of the Tayside Area Formulary have been reviewed and rationalised to reflect the most up-to-date evidence and encourage cost effective prescribing.

Key Messages:

- Offer women HRT as first line treatment for vasomotor symptoms and low mood / anxiety related to menopause after discussing the short and longer term benefits and risks.
- Offer vaginal oestrogen to women with vulvo-vaginal atrophy and urinary symptoms due to oestrogen deficiency (including those on systemic HRT) and continue treatment for as long as needed to relieve symptoms. There are very few contraindications to topical HRT.
- An individualised approach should be taken – the [NHS Tayside Flowchart for Systemic HRT Prescribing](#) can help guide choice of systemic HRT preparation – this also outlines

formulary 1st and 2nd line choices of systemic HRT preparations.

- Formulary systemic HRT changes include: **Removal of Estraderm® MX patches; Kliovance® instead of Elleste Duet® Conti (same pharmacological content); addition of Kliofem® as a lower dose alternative to Kliovance®/ Elleste Duet® Conti; addition of FemSeven® Sequi and FemSeven® Conti as 2nd choice after Evorel® Sequi and Evorel® Conti; estradiol 0.06% (Oestrogel®) transdermal gel added as an option particularly for patients who experience problems with patches due to skin reactions or poor patch adherence.**
- Advice on use of norethisterone and medroxyprogesterone acetate (MPA) has been updated particularly in relation to use in HRT (MPA) and to delay menstruation (MPA [off-label use] and norethisterone) in line with

latest evidence and in view of the higher VTE risk of norethisterone.

- **Estriol 0.1% intravaginal cream (Ovestin®) is the most cost effective topical HRT – now listed as a 1st choice topical HRT.** Estradiol 10mg vaginal tablets (Vagifem®) are an alternative 1st choice topical HRT preparation. 2nd choice topical HRT now includes: Estradiol vaginal ring (Estring®).
- Estriol 0.01% intravaginal cream (previously known as Gynest® cream) is now non-formulary as it is currently the **most expensive** topical HRT preparation.



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

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baricitinib 2mg and 4mg film-coated tablet (Olumiant®) SMC No (1265/17)

magnesium glycerophosphate 4mmol chewable tablet (Neomag®) SMC No (1267/17)

nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No (1261/17)

rolapitant (as hydrochloride monohydrate) 90mg film-coated tablets (Varuby®) SMC No (1266/17)

stiripentol 250mg and 500mg hard capsule, 250mg and 500mg powder for oral suspension in sachet (Diacomit®) SMC No (524/08)

September 2017 - SMC 'Not recommended' medicines

bevacizumab 25mg/mL concentrate for solution for infusion (Avastin®) SMC No (1275/17)

etelcalcetide 2.5mg, 5mg and 10mg solution for injection (Parsabiv®) SMC No (1262/17)

roflumilast, 500 microgram film-coated tablet (Daxas®) SMC No (635/10)

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beclometasone dipropionate/formoterol fumarate dihydrate/glycopyrronium 87mcg/5mcg/9mcg metered dose inhaler (Trimbow®) SMC No (1274/17)

daratumumab 20mg/mL concentrate for solution for infusion (Darzalex®) SMC No (1205/17)

sofosbuvir 400mg, velpatasvir 100mg film-coated tablets (Eplclusa®) SMC No (1271/17)

October 2017 - SMC 'Not recommended' medicines

maraviroc 20mg/mL oral solution, 25mg, 75mg, 150mg and 300mg film-coated tablets (Celsentri®) SMC No (1282/17)

opicapone 50mg hard capsules (Ongentys®) SMC No (1281/17)

Local implementation of SMC recommendations is taken forward by the Tayside Prescribing Support Unit (PSU). This bulletin is based on evidence available to Tayside PSU at time of publication and is covered by the Disclaimer and Terms & Conditions of Use.

New & Updated Formulary Links

Links updated or added within the formulary include:

[NICE Clinical Knowledge Summaries: Menopause](#)

[British Menopause Society – HRT Guide](#)

[NICE Guideline NG23 Menopause: diagnosis and management, Nov 2015](#)

[GP Update Red Whale Menstruation: postponing periods, June 2016](#)

Other Formulary Updates

The [Obstetrics & Gynaecology Specialist Formulary List](#) has been reviewed and updated.

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/medsearchmain.htm>

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.

Local processes exist to allow prescribing of non-SMC approved medicines for individual patients and are available in the [NHS Tayside Policy on the Prescribing of Medicines that are Non-formulary \(including Individual Patient Treatment Requests\)](#).

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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