



## Denosumab (Prolia®, Xgeva®▼): reports of osteonecrosis of the external auditory canal

Healthcare professionals are being advised to consider the possibility of osteonecrosis of the external auditory canal in patients receiving denosumab who present with ear symptoms including chronic ear infections. Patients should be advised to report any ear pain, discharge from the ear or an ear infection during denosumab treatment. The

product information for all denosumab containing products is being updated to include a warning on the risk of osteonecrosis of the external auditory canal.

See [Drug Safety Update, Volume 10, Issue 11, June 2017:1](#) for further details.

## MHRA Drug Safety Update

Daclizumab (Zinbryta® ▼) and risk of severe liver injury: initiation in multiple sclerosis now restricted, promptly review patients already on treatment.

[MHRA Risk of severe liver injury with daclizumab, July 2017](#)

## Brimonidine gel (Mirvaso®): risk of systemic cardiovascular effects; not to be applied to damaged skin

Brimonidine gel (Mirvaso®), an  $\alpha$ -2 adrenoceptor agonist is used for moderate to severe rosacea (green traffic light on the formulary). There have been reports of systemic cardiovascular effects including bradycardia, hypotension, and dizziness. To minimise possibility of systemic absorption, patients should be advised not to apply brimonidine gel to irritated or damaged skin, including after laser therapy.

See [Drug Safety Update, Volume 10, Issue 11, June 2017:2](#) for further details.

## Formulary Review: Contraceptives

[Section 07.03 of the Tayside Area Formulary](#) has been reviewed and rationalised to reflect the most up-to-date evidence and encourage cost-effective prescribing.

### Key Messages:

- **Combined hormonal contraceptives (CHC) – 1<sup>st</sup> choice: ethinylestradiol 30mcg/levonorgestrel 150mcg (Levest®)** current most cost-effective brand)
- Interchangeable brands for all relevant CHCs with most cost-effective brands now highlighted
- **Progestogen-only pill (POP) – 1<sup>st</sup> choice:**

desogestrel (prescribe generically). More expensive than other POPs but has a longer missed pill window and inhibits ovulation to a greater extent

- **Progestogen-only contraceptive injection – 1<sup>st</sup> choice: medroxyprogesterone acetate (Sayana Press®).** This is therapeutically equivalent to Depo-Provera® and is licensed for self-administration after training
- **Emergency Contraception** - All women requiring emergency contraception (EC) should be offered a **copper intra-uterine device (IUD) if appropriate as it is the most effective method of EC**

- **Emergency Hormonal Contraception (EHC) –** No longer a 1<sup>st</sup> choice preparation as the [FSRH Clinical Guidance: Emergency Contraception – March 2017](#) should be used by all health care professionals providing EC and referred to for choosing between ulipristal acetate EC and levonorgestrel EC (note: evidence suggests both are ineffective if taken after ovulation)
- **Now non-formulary: CHC - ethinylestradiol/gestodene (Millinette® 20/75, 30/75) and norethisterone (Micronor®/Noriday®)**

## Ascorbic Acid Duration

Ascorbic acid (Vitamin C) 500mg tablets (amber traffic light) are included in the 'Acute Pain Specialist List' for the prevention of chronic regional pain syndrome (CRPS) in trauma patients with chronic pain [off-label]. Prescribing is under the direction of the Acute Pain Team. The local protocol recommends 500mg ascorbic acid once daily for a total duration of 6 weeks.

This medicine is expensive if continued indefinitely (Drug Tariff Cost – 1 x 28 - £26.06). The indication/course length should therefore be clearly documented to ensure treatment is not continued for longer than is necessary.

For full information on any of the medicines listed below use the link to the Scottish Medicines Consortium (SMC) website below to search by generic, brand or SMC no.  
See NHS Tayside 'New Medicines' database (link below) for full details on Board decisions - these are currently listed alphabetically by page.

## Published SMC Advice

### 10 July 2017

aprepitant (Emend®) 80mg, 125mg hard capsules & 125mg powder for oral suspension SMC No. (1252/17)

ciprofloxacin 3mg/mL + dexamethasone 1mg/mL ear drops (Cilodex®) SMC No. (1256/17)

dolutegravir 10mg, 25mg, 50mg film-coated tablets (Tivicay®) SMC No. (1253/17)

glycopyrronium 320 micrograms/mL (glycopyrronium bromide 400 micrograms/mL) oral solution (Sialanar®) SMC No. (1254/17)

nivolumab 10mg/mL concentrate for solution for infusion (Opdivo®) SMC No. (1240/17)

pembrolizumab 50mg powder for concentrate for solution for infusion and 25mg/mL concentrate for solution for infusion (Keytruda®) SMC No. (1239/17)

saxagliptin 5mg/dapagliflozin 10mg film-coated tablets (Qtern®) SMC No. (1255/17)

ustekinumab 130mg concentrate for solution for infusion and 90mg solution for injection (Stelara®) SMC No. (1250/17)

### July 2017 - SMC 'Not recommended' medicines

emtricitabine tenofovir disoproxil 200mg/245mg film-coated tablets (Truvada®) SMC No. (1263/17)

selexipag, 200mcg, 400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg film-coated tablets (Uptrevi®) SMC No. (1235/17)

trametinib 0.5mg, 2mg film-coated tablets (Mekinist®) SMC No. (1264/17)

### 7 August 2017

carfilzomib 10mg, 30mg, 60mg powder for solution for infusion (Kyprolis®) SMC No. (1242/17)

desmopressin 25mcg, 50mcg oral lyophilisate (Noqdirna®) SMC No. (1218/17)

venetoclax, 10mg, 50mg and 100mg film-coated tablets (Venclyxto®) SMC No. (1249/17)

### August 2017 - SMC 'Not recommended' medicines

5-aminolaevulinic acid (as hydrochloride) 78mg/g gel (Ameluz®) SMC No. (1260/17)

canakinumab 150mg powder for solution for injection (Ilaris®) SMC No. (1268/17)

follitropin delta 12mcg, 36mcg and 72mcg solution for injection (Rekovelle®) SMC No. (1269/17)

sufentanil citrate 15mcg sublingual tablets (Zalviso®) SMC No. (1270/17)

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

[FSRH Clinical Guidance: Emergency Contraception, March 2017](#)

[FSRH Clinical Guidance: Drug Interactions with Hormonal Contraception, January 2017](#)

[FSRH Clinical Guidance: Quick Starting Contraception, April 2017](#)

[FSRH Clinical Effectiveness Unit \(CEU\) Statement: Self-Administration of Sayana Press®, September 2015](#)

[FSRH Clinical Guidance: Contraception for Women aged over 40 years, August 2017](#)

## Other Formulary Updates

Atropine sulphate 1% eye drops with preservative (10mL bottle) changed to atropine 1% Minims® (preservative free) due to cost.

Ciclosporin brand changed to Capimune® in line with updated [Ciclosporin Shared Care Agreement](#).

## Links to Additional Information

Monthly Drug Safety Updates:

[www.gov.uk/government/publications/drug-safety-update-monthly-newsletter](http://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](http://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 NHS Board decisions see Tayside Area Formulary - New Medicines database:

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

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 \(including Individual Patient Treatment Requests\)](#).

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.

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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