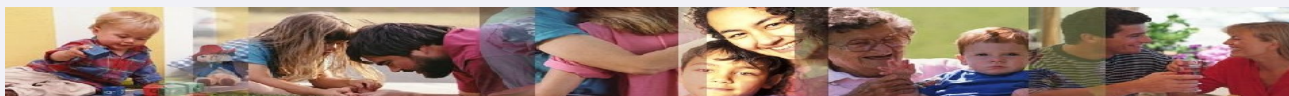


NEWSLETTER



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DENOSUMAB — PRESCRIBE BY BRAND

Denosumab is available in two strengths, given at different intervals and approved for use under different circumstances:

STRENGTH AND PRESENTATION	BRAND	DOSING SCHEDULE	INDICATION	STATUS
Denosumab 60mg/ml 1ml pre-filled syringe	Prolia® (review SPC here)	One injection (60mg) every SIX MONTHS	Treatment of <i>postmenopausal</i> osteoporosis, treatment of bone loss associated with hormone ablation in men with prostate cancer	AMBER LIST DRUG (see current shared care guidance here).
			Management of osteoporosis in men at increased risk of fractures	NOT ACCEPTED for use in NI (check full managed entry details here)
Denosumab 70 mg/mL 1.7mL (120mg) vial	XGEVA®▼ (review SPC here)	One injection (120mg) every FOUR WEEKS	Prevention of skeletal related events in adults with bone metastases from solid tumours	RED LIST DRUG (see red amber list here)

Recently there have been several prescribing and dispensing incidents involving denosumab:

- 'Denosumab 120mg' was prescribed and dispensed. This is a **RED LIST** drug and should be prescribed and supplied by secondary care only.
- XGEVA®▼ was intended but 2 x Prolia® was supplied and administered when the community pharmacy could not obtain XGEVA®▼.
- Prolia® was indicated but XGEVA®▼ was prescribed and dispensed with the directions for Prolia®.
- **In all cases the drug was written by generic name.**

Action

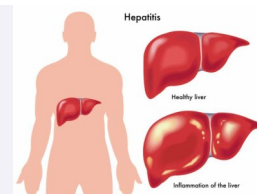
- Prescriptions for denosumab should be written by **BRAND NAME** to avoid confusion of similar products.
- XGEVA®▼ is a **RED LIST** drug and should only be prescribed and supplied by secondary care.
- If in doubt, check the Red Amber list at <http://www.ipnsm.hscni.net/library/RedAmberList.pdf>.
- Community pharmacists should refer back any prescription for a Red List drug to the prescriber.

FLUCLOXACILLIN AND HEPATIC DISORDERS

Prescribers are reminded that cholestatic jaundice and hepatitis may occur with flucloxacillin. Often the adverse reaction is delayed — most cases occur one week after discontinuation but can occur up to two months after treatment is stopped. Risk factors include:

- Administration for more than two weeks
- Increasing age (>55 years)
- Female gender

Refer to 'NI Management of Infection Guidelines for Primary Care' for recommended flucloxacillin indications:
<http://niformulary.hscni.net/Formulary/Adult/5.0/Pages/default.aspx>



SGLT2 INHIBITORS: RISK OF DIABETIC KETOACIDOSIS

Sodium-glucose cotransporter-2 (SGLT2) inhibitors include canagliflozin, dapagliflozin and empagliflozin. The European Medicines Agency (EMA) has started a [review of canagliflozin, dapagliflozin and empagliflozin](#), following reports of diabetic ketoacidosis (DKA) in patients on SGLT2 inhibitor treatment. All cases were serious and some required hospitalisation. Although DKA is usually accompanied by high blood sugar levels, in a number of these reports blood sugar levels were only moderately increased (e.g. <14 mmol/L or 250 mg/dL), which is atypical for DKA. This atypical presentation could delay diagnosis and treatment.

Action

The [MHRA](#) has advised that when treating patients who are taking an SGLT2 inhibitor:

- inform patients of the symptoms and signs of DKA (e.g. nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness) and advise them to get immediate medical help if these occur
- test for raised ketones in patients with symptoms of DKA; omitting this test could delay diagnosis of DKA
- if you suspect DKA, stop SGLT2 inhibitor treatment
- if DKA is confirmed, take appropriate measures to correct the DKA and to monitor glucose levels
- be aware that SGLT2 inhibitors are licensed for treatment of type 2 diabetes and are not approved for treatment of type 1 diabetes
- please continue to report suspected side effects to SGLT2 inhibitors or any other medicines on a [Yellow Card](#).

IV MEDUSA GUIDE REMOVED

The IV Medusa guide has been removed from the resources page on the Primary Care intranet. Regional Medicines and Poisons Information Service continue to have access to Medusa and can be contacted for queries regarding parenteral administration of medicines. Tel: 028 9504 0558. E-mail: nirdic.nirdic@belfasttrust.hscni.net



NEW NICE GUIDANCE

[NICE Guideline NG11](#) — Challenging behaviour and learning disabilities.

[NICE Guideline NG10](#) — Violence and aggression (update).

[NICE Guideline NG9](#) — Bronchiolitis in children

MANAGED ENTRY DECISIONS

The following medicines were considered in June as part of the Northern Ireland Managed Entry process. **For details of the outcomes please refer to the Managed Entry section of the Northern Ireland Formulary website:** <http://niformulary.hscni.net/ManagedEntry/MEDecisions/Pages/default.aspx>

Primary and Secondary Care

- Budesonide (Budenofalk[®])
- Levonorgestrel (Levosert[®])
- Linagliptin + metformin combination tablets (Jentadueto[®])
- Magnesium aspartate dihydrate (Magnaspartate[®])
- Naloxegol (Moventig[®])

Secondary Care

- Adalimumab (Humira[®])
- Cangrelor (Kengrexal[®])
- Obinutuzumab (Gazyvaro[®])
- Ponatinib (Iclusig[®])
- Regorafenib (Stivarga[®])
- Sucroferric oxyhydroxide (Velphoro[®])

This newsletter has been produced for GPs and Pharmacists by the Regional Pharmacy and Medicines Management Team. If you have any queries or require further information on the contents of this newsletter, please contact one of the Medicines Management pharmacists in your local HSCB office.

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References

- 1) MHRA. SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin): risk of diabetic ketoacidosis. Drug Safety Update, June 2015.
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- 7) Russmann S et al. Risk of cholestatic liver disease associated with flucloxacillin and flucloxacillin prescribing habits in the UK: Cohort study using data from the UK General Practice Research Database. Br J Clin Pharmacol. 2005 Jul; 60(1): 76–82.
- 9) BSO. Prescribing data 2014.

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