Think Medicines!

NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Issue 8
March 2016

Safety

Denosumab, Bisphosphonates, Galantamine, Mirena & Nicorandil

Denosumab: Minimizing the risk of osteonecrosis of the jaw

In October 2014 we reported on Denosumab being associated with a risk of both osteonecrosis of the jaw (ONJ) and hypocalcaemia.

A recent Drug Safety Update advises on further measures to minimize risks of ONJ:

- Patient reminder cards about the risk of osteonecrosis of the jaw are available by searching the individual product on the electronic Medicines Compendium.
- Denosumab 120 mg (cancer indication) is now contraindicated in patients with unhealed lesions from dental or oral surgery.

Patients should be advised to:

- Tell their doctor if they have any problems with their mouth or teeth, including ill fitting dentures, before starting treatment.
- Maintain good oral hygiene.
- Receive routine dental check-ups.
- Tell their doctor and dentist immediately if they have any problems with their mouth or teeth during treatment with denosumab (e.g. loose teeth, pain, swelling, non-healing sores or discharge).
- Tell their dentist that they are receiving denosumab if they need dental treatment or dental surgery.

https://www.gov.uk/drug-safety-update/denosumab-xgeva-prolia-intravenous-bisphosphonates-osteonecrosis-of-the-jaw-further-measures-to-minimise-risk

Bisphosphonates: Very rare reports of osteonecrosis of the external auditory canal

Osteonecrosis of the external auditory canal has been reported very rarely (with bisphosphonates, mainly in association with long-term therapy (2 years or longer).

Advice for healthcare professionals:

- The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving bisphosphonates who present with ear symptoms, including chronic ear infections, or in patients with suspected cholesteatoma.
- Possible risk factors include steroid use and chemotherapy, with or without local risk factors such as infection or trauma.
- Patients should be advised to report any ear pain, discharge from the ear, or an ear infection during bisphosphonate treatment.
- Report any cases of osteonecrosis of the external auditory canal suspected to be associated with bisphosphonates or any other medicines, including denosumab, on a Yellow Card.

Please continue to report suspected ADRs on a Yellow Card. The quickest and easiest way is online.

https://yellowcard.mhra.gov.uk

Medicines Management Team capccg.prescribingpartnership@nhs.net 01480 387126

Think Medicines!

NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Safety

Galantamine hydrobromide: serious skin reactions

Serious skin conditions had been reported in people taking galantamine hydrobromide (Reminyl®). These included Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP) and erythema multiforme (EM).

Patients should be advised to watch out for signs of serious skin reactions which include:

- Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (SJS).
- Red rash covered with small pus-filled bumps that can spread over the body, sometimes with fever (AGEP).
- Rash that may blister, with spots that look like small targets (EM).

Stop galantamine hydrobromide treatment and get medical help immediately if they notice any of the above.

Intrauterine systems releasing 52mg Levonorgestrel: prescribe by brand name

Intrauterine systems releasing levonorgestrol should be prescribed by **BRAND NAME** to differentiate between indications, duration of use and introducers.

Mirena® - **releasing 52mg Levonorgestrel: Licensed for** contraception (5 years), heavy menstrual bleeding (5 years) or endometrial protection as part of a hormone-replacement therapy regimen (4 years).

Levosert® - **releasing 52mg Levonorgestrel:** Licensed for contraception or heavy menstrual bleeding (3 years).

IUDs should only be inserted by healthcare professionals who are experienced in insertion or who have had training in the relevant insertion techniques.

Nicorandil: Risk of serious ulceration

Nicorandil can cause serious skin, mucosal, and eye ulceration, including gastrointestinal ulcers which may progress to perforation, haemorrhage, fistula, or abscess unless treatment is discontinued.

Advice for healthcare professionals:

- Use nicorandil for treatment of stable angina only in patients whose angina is inadequately controlled by first line anti-angina therapies, or who have a contraindication or intolerance to anti-angina therapies such as beta-blockers or calcium antagonists
- Stop nicorandil and consider alternative treatment if ulceration occurs on any part of the body
- Patients with diverticular disease or taking nicorandil concomitantly with aspirin, NSAIDs or corticosteroids may be at particular risk.

Medicines Management Team capccg.prescribingpartnership@nhs.net 01480 387126