

- the manufacturer provides denosumab with the discount agreed in the patient access scheme. Denosumab is **not** recommended for preventing skeletal-related events in adults with bone metastases from prostate cancer.

Patients with bone metastases from solid tumours currently receiving denosumab whose disease does not meet the above criteria can continue treatment until they and their clinician consider it appropriate to stop.

[www.nice.org.uk/guidance/ta265](http://www.nice.org.uk/guidance/ta265)

#### Scottish Medicines Consortium (SMC) decisions

SMC No. 651/10

The *Scottish Medicines Consortium* has advised (December 2010) that denosumab (*Prolia*®) is accepted for restricted use within NHS Scotland for the treatment of osteoporosis in postmenopausal women at increased risk of fractures who have a bone mineral density T-score < -2.5 and ≥ -4.0 and for whom oral bisphosphonates are unsuitable.

- MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

#### Solution for injection

CAUTIONARY AND ADVISORY LABELS 10  
EXCIPIENTS: May contain Sorbitol

- ▶ **Prolia** (Amgen Ltd)

**Denosumab 60 mg per 1 ml** Prolia 60mg/1ml solution for injection pre-filled syringes | 1 pre-filled disposable injection [PoM] £183.00 DT = £183.00

- ▶ **Xgeva** (Amgen Ltd)

**Denosumab 70 mg per 1 ml** Xgeva 120mg/1.7ml solution for injection vials | 1 vial [PoM] £309.86 DT = £309.86

medicines must be prescribed and dispensed by brand name, see *Biological medicines* and *Biosimilar medicines*, under Guidance on prescribing p. 1.

The manufacturer of *Evenity*® has provided a *Prescriber Guide*.

- **HANDLING AND STORAGE** Manufacturer advises store in a refrigerator (2–8°C) and protect from light—consult product literature for further information regarding storage outside the refrigerator.
- **PATIENT AND CARER ADVICE** Atypical femoral fractures Manufacturer advises patients should be advised to report any new or unusual thigh, hip, or groin pain during treatment. Osteonecrosis of the jaw Manufacturer advises patients should be informed to maintain good oral hygiene, receive routine dental check-ups, and immediately report any oral symptoms such as dental mobility, pain, or swelling. Hypocalcaemia Manufacturer advises patients should be advised to report symptoms of hypocalcaemia. Patients should receive a package leaflet and patient alert card.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

#### Solution for injection

EXCIPIENTS: May contain Polysorbates

- ▶ **Evenity** (UCB Pharma Ltd) ▼

**Romosozumab 90 mg per 1 ml** Evenity 105mg/1.17ml solution for injection pre-filled pens | 2 pre-filled disposable injection [PoM] £427.75

## Romosozumab

23-Apr-2020

- **DRUG ACTION** Romosozumab is a humanised monoclonal antibody that inhibits sclerostin, thereby increasing bone formation and decreasing bone resorption.

#### • INDICATIONS AND DOSE

**Severe osteoporosis in postmenopausal women at increased risk of fractures (specialist use only)**

- ▶ BY SUBCUTANEOUS INJECTION

- ▶ **Adult:** 210 mg once a month for 12 months, supplement with calcium and vitamin D, to be administered as two consecutive 105 mg injections at different injection sites into the thigh, abdomen or upper arm

- **CONTRA-INDICATIONS** History of myocardial infarction or stroke—discontinue if occurs during treatment · hypocalcaemia
- **CAUTIONS** Risk factors for cardiovascular disease · risk factors for osteonecrosis of the jaw—consider temporary interruption of romosozumab if occurs during treatment
- **SIDE-EFFECTS**
  - ▶ **Common or very common** Arthralgia · headache · hypersensitivity · increased risk of infection · muscle spasms · neck pain · skin reactions
  - ▶ **Uncommon** Cataract · hypocalcaemia · myocardial infarction · stroke
  - ▶ **Rare or very rare** Angioedema
  - ▶ **Frequency not known** Atypical femur fracture · cardiovascular event · osteonecrosis of jaw
- **RENAL IMPAIRMENT** Manufacturer advises monitor serum calcium concentration in patients with severe renal impairment, or in those receiving dialysis—increased risk of hypocalcaemia.
- **MONITORING REQUIREMENTS** Manufacturer advises to correct hypocalcaemia before therapy is initiated. Monitor for signs and symptoms of hypocalcaemia during therapy.
- **PRESCRIBING AND DISPENSING INFORMATION** Romosozumab is a biological medicine. Biological

## 5 Dopamine responsive conditions

### DOPAMINERGIC DRUGS > DOPAMINE RECEPTOR AGONISTS

## Dopamine-receptor agonists

### Overview

Bromocriptine p. 439 is used for the treatment of galactorrhoea, and for the treatment of prolactinomas (when it reduces both plasma prolactin concentration and tumour size). Bromocriptine also inhibits the release of growth hormone and is sometimes used in the treatment of acromegaly, but somatostatin analogues (such as octreotide p. 1002) are more effective.

Cabergoline p. 440 has similar side-effects to bromocriptine, however patients intolerant of bromocriptine may be able to tolerate cabergoline (and *vice versa*).

Quinagolide p. 777 has actions and uses similar to those of ergot-derived dopamine agonists, but its side-effects differ slightly.

### Suppression of lactation

Although bromocriptine and cabergoline are licensed to suppress lactation, they are **not** recommended for routine suppression (or for the relief of symptoms of postpartum pain and engorgement) that can be adequately treated with simple analgesics and breast support. If a dopamine-receptor agonist is required, cabergoline is preferred. Quinagolide is not licensed for the suppression of lactation.