LORON 520 ®

Osteolytic lesions, hypercalcaemia and bone pain associated with skeletal metastases in patients with breast cancer or multiple myeloma

- BY MOUTH
- Adult: Initially 2 tablets daily in 1–2 divided doses, increased if necessary up to 4 tablets daily

- **CONTRA-INDICATIONS** Acute severe gastro-intestinal inflammatory conditions
- **CAUTIONS** Atypical femoral fractures · maintain adequate fluid intake during treatment · upper gastro-intestinal disorders
- **INTERACTIONS** → Appendix 1: bisphosphonates
- **SIDE-EFFECTS** Proteinuria · respiratory disorder
- **PREGNANCY** Avoid.
- **BREAST FEEDING** Manufacturer advises avoid—no information available.
- **RENAL IMPAIRMENT** Avoid if eGFR less than 10 mL/minute/1.73 m^2.
  Dose adjustments Max. initial dose 1200 mg daily if eGFR 30-50 mL/minute/1.73m^2.
  Use half normal dose if eGFR 10–30 mL/minute/1.73 m^2.
- **MONITORING REQUIREMENTS** Monitor renal function, serum calcium and serum phosphate before and during treatment.
- **DIRECTIONS FOR ADMINISTRATION** Avoid food for 2 hours before and 1 hour after treatment, particularly calcium-containing products e.g. milk; also avoid iron and mineral supplements and antacids; maintain adequate fluid intake.
- **PATIENT AND CARER ADVICE** Patients or carers should be given advice on how to administer sodium clodronate capsules and tablets.

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

Tablet

CAUTIONARY AND ADVISORY LABELS 10

- **Bonefos** (Bayer Plc)
  Sodium clodronate 800 mg Bonefos 800mg tablets | 60 tablet PoM £146.43 DT = £146.43
- **Clasteon** (Kent Pharmaceuticals Ltd)
  Sodium clodronate 800 mg Clasteon 800mg tablets | 60 tablet PoM £146.43 DT = £146.43
- **Loron** (Intrapharm Laboratories Ltd)
  Sodium clodronate 520 mg Loron 520mg tablets | 60 tablet PoM £114.44 DT = £114.44

Capsule

- **Sodium clodronate (Non-proprietary)**
  Sodium clodronate 400 mg Sodium clodronate 400mg capsules | 30 capsule PoM £34.96 | 120 capsule PoM £139.83 DT = £139.83
- **Bonefos** (Bayer Plc)
  Sodium clodronate 400 mg Bonefos 400mg capsules | 120 capsule PoM £139.83 DT = £139.83
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  Sodium clodronate 400 mg Clasteon 400mg capsules | 30 capsule PoM £34.96 | 120 capsule PoM £139.83 DT = £139.83

765

Zoledronic acid

23-Mar-2020

- **INDICATIONS AND DOSE**

Prevention of skeletal related events in advanced malignancies involving bone (specialist use only)

- BY INTRAVENOUS INFUSION
- Adult: 4 mg every 3–4 weeks, calcium 500 mg daily and vitamin D 400 units daily should also be taken

Tumour-induced hypercalcaemia (specialist use only)

- BY INTRAVENOUS INFUSION
- Adult: 4 mg for 1 dose

Paget's disease of bone (specialist use only)

- BY INTRAVENOUS INFUSION
- Adult: 5 mg for 1 dose, at least 500 mg elemental calcium twice daily (with vitamin D) for at least 10 days is recommended following infusion

Osteoporosis (including corticosteroid-induced osteoporosis) in men and postmenopausal women

- BY INTRAVENOUS INFUSION
- Adult: 5 mg once yearly as a single dose, in patients with a recent low-trauma hip fracture, the dose should be given at least 2 weeks after hip fracture repair; before first infusion give 50 000–125 000 units of vitamin D

- **CAUTIONS** Atypical femoral fractures · cardiac disease (avoid fluid overload) · concomitant medicines that affect renal function
- **INTERACTIONS** → Appendix 1: bisphosphonates
- **SIDE-EFFECTS**
  - **Common or very common** Appetite decreased · chills · flushing
  - **Uncommon** Anaphylactic shock · anxiety · arrhythmias · chest pain · circulatory collapse · cough · drowsiness · dry mouth · dyspnoea · haematuria · hyperhidrosis · hypertension · hypotension · leucopenia · muscle spasms · proteinuria · respiratory disorders · sensation abnormal · sleep disorder · stomatitis · syncope · thrombocytopenia · tremor · vision blurred · weight increased
  - **Rare or very rare** Confusion · Fanconi syndrome acquired · pancytopenia
  - **Frequency not known** Acute phase reaction

  SIDE-EFFECTS, FURTHER INFORMATION Renal impairment and renal failure have been reported; ensure patient is hydrated before each dose and assess renal function.
- **CONCEPTION AND CONTRACEPTION** Contra-indicated in women of child-bearing potential.
- **PREGNANCY** Avoid—toxicity in *animal* studies.
- **BREAST FEEDING** Avoid—no information available.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in severe hepatic impairment (limited information available).
- **RENAL IMPAIRMENT** Avoid in tumour-induced hypercalcaemia if serum creatinine above 400 micromol/litre. Avoid in advanced malignancies involving bone if eGFR less than 30 mL/minute/1.73 m^2 (or if serum creatinine greater than 265 micromol/litre). Avoid in Paget's disease, treatment of postmenopausal osteoporosis and osteoporosis in men if eGFR less than 35 mL/minute/1.73 m^2.
  Dose adjustments In advanced malignancies involving bone, if eGFR 50–60 mL/minute/1.73 m^2 reduce dose to 3.5 mg every 3–4 weeks; if eGFR 40–50 mL/minute/1.73 m^2 reduce dose to 3.3 mg every 3–4 weeks; if eGFR 30–40 mL/minute/1.73 m^2 reduce dose to 3 mg every 3–4 weeks; if renal function deteriorates in patients with bone metastases, withhold dose until serum creatinine returns to within 10% of baseline value.
- **MONITORING REQUIREMENTS**
  - Correct disturbances of calcium metabolism (e.g. vitamin D deficiency, hypocalcaemia) before starting. Monitor serum electrolytes, calcium, phosphate and magnesium.
  - Monitor renal function in patients at risk, such as those with pre-existing renal impairment, those of advanced age, those taking concomitant nephrotoxic drugs or diuretics, or those who are dehydrated.
- **DIRECTIONS FOR ADMINISTRATION**
  - When used for Prevention of skeletal related events in advanced malignancies involving bone or Tumour-induced hypercalcaemia For *intravenous infusion*, infuse over at least 15 minutes; administer as a single intravenous solution in a separate infusion line. If using 4 *mg/5 mL concentrate for*