Bondronat® (ibandronic acid) film-coated tablets and solution for infusion

Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing

Presentation: Bondronat tablets contain 50mg ibandronic acid (sodium monohydrate). Bondronat concentrate for solution for infusion contains ibandronic acid (sodium monohydrate) 1 mg/ml in 2 ml and 6 ml glass vials.

Solution for infusion requires dilution prior to administration as an intravenous infusion.

Indication: Bondronat tablets and solution for infusion are indicated in adults for the prevention of skeletal events (pathological fractures, bone complications requiring radiotherapy or surgery) in patients with breast cancer and bone metastases. Bondronat solution for infusion is also indicated for the treatment of tumour-induced hypercalcaemia with or without metastases.

Dosage and administration: Bondronat should only be initiated by a physician experienced in cancer treatment. Bondronat tablets dose: One tablet daily. Tablet to be taken after overnight fast (6 hours min.) and before first food or drink of the day. Continue fast for 30 minutes after taking. Tablet should be swallowed whole, with 180-240ml water (no other drink) whilst standing or sitting upright. Patient should not use water with high calcium content (hard water) nor lie down for an hour after taking tablet. Other medicinal products and supplements should be avoided prior to taking Bondronat tablets and for at least 30 minutes afterwards. Bondronat solution for infusion dose: Patients to be given package leaflet and patient reminder card. Prevention of skeletal events dose: 6 mg intravenous injection given every 3-4 weeks. Content of vial to be added to 100ml isotonic sodium chloride solution or 100ml 5% dextrose solution and infused intravenously over at least 15 minutes. A 15 min infusion time should only be used in patients with normal renal function or mild renal impairment. Treatment of tumour-induced hypercalcaemia dose: Patient should be adequately rehydrated with 0.9% sodium chloride solution prior to treatment with Bondronat and consideration given to the severity of the hypercalcaemia as well as tumour type. 2 mg is an effective dose in patients with moderate hypercalcaemia and 4 mg in severe hypercalcaemia. Patients with osteolytic bone metastases usually require lower doses than those with humoral type of hypercalcaemia. Content of vial to be added to 500ml isotonic sodium chloride solution or 500ml 5% dextrose solution and administered as a single intravenous infusion over 2 hours. Repeated treatment may be considered in case of recurrent hypercalcaemia or insufficient efficacy. For patients with renal impairment refer to full prescribing information for both tablets and infusion dose details in this patient group.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Hypocalcaemia. Bondronat tablets only: Abnormalities of the oesophagus which delay oesophageal emptying or inability to stand or sit upright for at least 60 minutes.

Special warnings and precautions: Disturbances of bone and mineral metabolism should be effectively treated before starting Bondronat and adequate intake of calcium and vitamin D, via supplements if dietary intake inadequate. Anaphylactic reaction/shock have been reported with intravenous administration of ibandronic acid. Appropriate support and monitoring measures should be readily available and infusion immediately discontinued if reactions occur. Osteonecrosis of the jaw (ONJ) has rarely been reported in post-marketing setting in patients receiving Bondronat for oncology indications. Risk factors including potency of bone resorption inhibition given, cancer, co-morbid conditions, smoking, concomitant therapies and poor oral hygiene, periodontal or dental disease and dental procedures should be considered. Bondronat treatment initiation or start of a new course should be delayed in patients with healed open soft tissue mouth lesions. Osteonecrosis of external auditory canal (OEAC) has been reported with bisphosphonates, mainly in long term therapy; with concomitant steroid use and chemotherapy and/or local risk factors (infection or trauma). OEAC should be considered in patients presenting with ear symptoms including chronic ear infections. Atypical fractures of the femur have been reported with bisphosphonates, primarily in long term treatment for osteoporosis. Patients should be advised to report any thigh, hip or groin pain and evaluation conducted for an incomplete femur fracture. Discontinuation of treatment should be considered pending evaluation. It is recommended that renal function, serum calcium, phosphate and magnesium should be monitored in patients on Bondronat. Overhydration should be avoided in patients at risk of cardiac failure. No dose recommendation can be made in severe hepatic failure as no clinical data available. Caution should be taken in patients with known hypersensitivity to other bisphosphonates or concomitant aminoglycoside treatment. Bondronat tablets only; rare lactose intolerance/deficiency disorders and gastrointestinal irritation. Caution in patients with active upper gastrointestinal problems, concomitant NSAID use (including aspirin) and in those who do not comply with dosing instructions or continue to take after developing symptoms such as dysphagia, odynophagia, retrosternal pain or new/worsening heartburn. Gastric and duodenal ulcers have been reported with oral bisphosphonates. For further information on special warnings, precautions and interactions please refer to SmPC.

Pregnancy and lactation: Bondronat should not be used during pregnancy or whilst breastfeeding.

Undesirable effects: Tablets; Most frequent adverse events are hypocalcaemia and dyspepsia. Incidence of undesirable effects for oral administration; Very common: §1/10; None noted; Common §1/100 to <1/10; Hypocalcaemia, oesophagitis, abdominal pain, dyspepsia, nausea and asthenia. Bondronat infusion, treatment of tumour-induced hypercalcaemia; The most frequently reported adverse reactions are a rise in body temperature and hypocalcaemia. In most cases no specific treatment is required and symptoms subside after a couple of hours/days. Bondronat infusion, prevention of skeletal events; Asthenia, rise in body temperature and headache are most frequent noted events. Incidence of undesirable effects for intravenous infusion administration; Very common: §1/10; None noted; Common §1/100 to <1/10; Infection, parathyroid disorder, hypocalcaemia, headache, dizziness, dysgeusia, cataract, bundle branch block, pharyngitis, diarrhoea, vomiting, dyspepsia, gastrointestinal pain, tooth disorder, skin disorder, ecchymosis, osteoarthritis, myalgia, arthralgia, joint disorder, bone pain, pyrexia, influenza like illness, oedema peripheral, asthenia, thirst, gamma GT and creatinine increases. Serious adverse reactions; Anaphylactic reaction/shock, atypical fractures of the femur, osteonecrosis of the jaw and ocular inflammation. Refer to SmPC for full details.

Legal category: POM. Presentation and Cost: 50 mg tablets (28) £183.69, 2 mg /2 ml vial £89.36 and 6 mg /6 ml vial £183.69. Marketing authorisation holder and numbers: Atnahs Pharma Netherlands B.V. Strawinskylaan 3127, Netherlands. 2 mg vial EU/1/96/012/004, 6 mg vial EU/1/96/012/011. Tablets EU/1/96/012/009. Further information is available from Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon SS14 3FR, UK. Date of last revision: January 2020

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Atnahs Pharma UK Limited on +44 (0) 1279 406759 or by email to atnahsvp@diamondpharmaservices.com