Prescribing Information.

Bomyntra▼(Denosumab). This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Denosumab 120 mg solution for injection in pre-filled syringe, denosumab 120 mg solution for injection in vial**.** Consult the Summary of Product Characteristics (SmPC) before prescribing. Additional information is available on request. **Presentations and Active Ingredients:** Each pre-filled syringe and vial contains 120 mg of denosumab in 1.7 mL of solution (70 mg/mL). **Indication:** ***Pre-filled syringe & solution for injection in vial:*** Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone. Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity. **Dosage:** For subcutaneous use**.** Supplementation of at least 500 mg calcium and 400 IU vitamin D daily is required in all patients, unless hypercalcaemia is present. Patients should be given the package leaflet and the patient reminder card. ***Prevention of skeletal related events in adults with advanced malignancies involving bone:*** Single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm. ***Giant cell tumour of bone:*** Single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm with additional 120 mg doses on days 8 and 15 of treatment of the first month of therapy. Patients with giant cell tumour of bone require regular evaluation to assess ongoing benefit from treatment. ***Renal impairment:*** No dose adjustment is required in patients with renal impairment. ***Hepatic impairment:*** Safety and efficacy of denosumab has not been studied in patients with hepatic impairment. ***Elderly patients (age ≥ 65):*** No dose adjustment is required. ***Paediatric population:*** Safety and efficacy not established in paediatric patients (age < 18) other than skeletally mature adolescents (aged 12-17 years) with giant cell tumour of bone. Denosumab is not recommended in paediatric patients (age < 18) other than skeletally mature adolescents (aged 12-17 years) with giant cell tumour of bone. Treatment of skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity: the posology is the same as in adults. **Administration**: ***Prefilled syringe:*** Can be administered by a patient or caregiver who has been trained in injection techniques by a healthcare professional; first self-administration should be supervised. ***Solution for injection in vial:*** Should only be performed by a healthcare professional. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients (see SmPC). Severe, untreated hypocalcaemia. Unhealed lesions from dental or oral surgery. **Warnings and Precautions:** To ensure traceability of biological medicinal products, the name and batch number must be clearly recorded. Calcium and vitamin D supplementation is essential for all patients unless hypercalcaemia is present. Pre-existing hypocalcaemia should be corrected before starting denosumab, as it may occur anytime during treatment. Calcium levels must be monitored before the first dose, within two weeks after, and if symptoms arise. Additional monitoring is advised for patients with additional risk factors or if otherwise indicated. Patients should report any symptoms indicative of hypocalcaemia. If hypocalcaemia develops, further supplementation and monitoring may be needed. Severe cases, including fatalities, have been reported, mostly within the first weeks of therapy. Patients with severe renal impairment (CrCl<30mL/min) or on dialysis are at higher risk and require regular calcium level checks. Risk of hypocalcaemia and elevations in parathyroid hormone increases with increasing degree of renal impairment. Osteonecrosis of the jaw (ONJ) reported commonly with denosumab. Delay treatment if unhealed open soft tissue lesions in mouth. Dental examination with preventative dentistry and individual risk-benefit assessment recommended prior to denosumab. Consider following risk factors: potency of bone resorption inhibitor, route of administration, cumulative dose of bone resorption therapy, cancer, co-morbidities, smoking, concomitant therapies (corticosteroids, chemotherapy, angiogenesis

inhibitors, radiotherapy to head and neck), poor oral health and/or hygiene, invasive dental procedures. Patients should maintain good oral hygiene, undergo routine dental check-ups, and report oral symptoms immediately; perform invasive dental procedures only after careful consideration and avoid in close proximity to denosumab administration. ONJ management requires collaboration between treating physician and dental specialists, with possible treatment interruption. Denosumab has also been linked to osteonecrosis of the external auditory canal; consider if ear symptoms including chronic ear infections. Possible risk factors include steroid use, chemotherapy, or local infections/trauma. Atypical femoral fractures may occur with little/no trauma in subtrochanteric and diaphyseal regions of femur and reported in certain co-morbid conditions and medications (see SmPC). Contralateral femur should be examined in denosumab treated patients with femoral shaft fracture. Consider denosumab discontinuation in suspected atypical femur fracture. Patients should report new/unusual thigh, hip, or groin pain; evaluate for incomplete femoral fracture. Weeks to months post-treatment discontinuation, clinically significant hypercalcaemia complicated by acute renal injury and requiring hospitalisation reported in patients with giant cell tumour of bone. Monitor for hypercalcaemia post-discontinuation; consider periodic serum calcium assessment and calcium and vitamin D supplementation adjustment. Denosumab should not be used concurrently with other denosumab products or bisphosphonates. Though rare, malignancy or metastasis in giant cell tumour of bone patients is a known risk, warranting radiological monitoring, although current data does not indicate increased malignancy risk with denosumab. This medication includes sorbitol. When taken alongside other products containing sorbitol or fructose, as well as dietary sources of these substances, their combined effects should be considered. This medicine contains 0.17 mg of polysorbate 20. Polysorbates may trigger allergic reactions. Inform your healthcare provider if you have any known allergies. Contains less than 1 mmol of sodium (23 mg) per 120 mg dose, essentially sodium-free. **Interactions:** No interaction studies have been performed. Clinical trials show no clinically relevant alterations to denosumab's trough serum concentration and pharmacodynamics by concomitant chemotherapy, hormone therapy, or previous intravenous bisphosphonate exposure. **Pregnancy and lactation:** Bomyntra is not recommended for use in pregnant women and women of child-bearing potential not using contraception. Women should be advised not to become pregnant during and for at least 5 months after treatment with denosumab. A decision must be made on whether to abstain from breast-feeding or to abstain from Bomyntra therapy taking into account the benefit of breast-feeding to the newborn/infant and the benefit of therapy for the woman. **Adverse Reactions:** Very common ≥ 1/10: Hypocalcaemia, dyspnoea, diarrhoea, musculoskeletal pain. Common ≥ 1/100 to < 1/10: New primary malignancy, hypophosphataemia, tooth extraction, hyperhidrosis, osteonecrosis of the jaw. In the post-marketing setting, events of hypersensitivity, including rare events of anaphylactic reactions, have been reported in patients receiving denosumab. Uncommon (≥ 1/1 000 to < 1/100) serious: Hypercalcaemia following discontinuation, atypical femoral fracture. Rare (≥ 1/10 000 to < 1/1 000) serious: Drug hypersensitivity, anaphylactic reaction; Not known frequency serious: Osteonecrosis of the external auditory canal. Prescribers should consult the summary of product characteristics in relation to other adverse reactions. **Pack Sizes:** ***Ireland:*** *120 mg vial & Bomyntra 120mg PFS (cost of Pack sizes of 1):* €170.72**.** ***United Kingdom:*** *120 mg vial & Bomyntra 120mg PFS (cost of Pack sizes of 1):* £278.91**. Legal Category:** POM. **Marketing Authorisation Numbers:** ***Ireland:*** Bomyntra 120 mg PFS: EU/1/25/1953/04 EU/1/25/1953/05, EU/1/25/1953/06. Bomyntra 120 mg vial: EU/1/25/1953/01, EU/1/25/1953/02 EU/1/25/1953/03. ***United Kingdom:*** Bomyntra 120 mg PFS: PL 08828/0382. Bomyntra 120 mg vial: PL 08828/0383. **Marketing Authorisation Holder:** ***Ireland:*** Fresenius Kabi Deutschland GmbH, Else-Kroener-Strasse 1, 61352 Bad Homburg von der Hoehe, Germany. ***United Kingdom:*** Fresenius Kabi Limited, Cestrian Court, Eastgate Way, Manor

Park Runcorn, Cheshire, WA7 1NT, United Kingdom. **Further Information:** See the SmPC for further details. **Date of Preparation:** December 2025. **Job Code**: IE-BOM-2500002

Adverse events should be reported. Reporting forms and information can be found at: https://yellowcard.mhra.gov.uk Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL — Dublin 2, Tel: +353 1 6764971, Fax: +353-1-6764061. Website: www.hpra.ie/report-an-issue E-mail: medsafety@hpra.ie. Adverse events should also be reported to Fresenius Kabi Ltd. Cestrian Court, Eastgate Way, Manor Park, Runcorn, Cheshire, WA7 1NT Tel +44 (0)1928 533 575 via email: pharmacovigilance.gb@fresenius-kabi.com