DENSUCOR

To be sold by retail on the prescription of an Endocrinologist, Rheumatologist and Orthopedicians only

Abbreviated Prescribing information for DENSUCOR [Denosumab 60 mg/mL (r-DNA origin) in prefilled syringe]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Denosumab is a human monoclonal antibody (IgG2) that targets and binds with high affinity and specificity to RANKL, preventing activation of its receptor, RANK, on the surface of osteoclast precursors and osteoclasts. Prevention of the RANKL/ RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption in cortical and trabecular bone.

INDICATION: 1. Treatment of osteoporosis in postmenopausal women. 2. Treatment to increase bone mass in men with osteoporosis at high risk of fracture. 3. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. 4. Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. 5. Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.

DOSAGE AND ADMINISTRATION: The recommended dose is 60 mg denosumab administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or upper arm. For subcutaneous use. Administration should be performed by an individual who has been adequately trained in injection techniques.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Hypocalcaemia.

WARNINGS & PRECAUTIONS: Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy. Clinical monitoring of calcium levels is recommended before each dose and, in patients predisposed to hypocalcaemia within two weeks after the initial dose. The risks of developing hypocalcaemia and accompanying parathyroid hormone elevations increase with increasing degree of renal impairment. Patients receiving denosumab may develop skin infections (predominantly cellulitis) leading to hospitalisation. Temporary discontinuation of treatment should be considered until Osteonecrosis of jaw resolves and contributing risk factors are mitigated where possible. Discontinuation of denosumab therapy in patients suspected to have an atypical femur fracture should be considered pending evaluation of the patient based on an individual benefit risk assessment.

DRUG INTERACTIONS: In an interaction study, denosumab did not affect the pharmacokinetics of midazolam, which is metabolised by cytochrome P450 3A4 (CYP3A4). This indicates that denosumab should not alter the pharmacokinetics of medicinal products metabolised by CYP3A4.There are no clinical data on the co-administration of denosumab and hormone replacement therapy (estrogen), however the potential for a pharmacodynamic interaction is considered to be low. In postmenopausal women with osteoporosis the pharmacokinetics and pharmacodynamics of denosumab were not altered by previous alendronate therapy, based on data from a transition study (alendronate to denosumab).

ADVERSE REACTIONS: Urinary tract infection, upper respiratory tract infection, nasopharyngitis, diverticulitis cellulitis, ear infection, drug hypersensitivity, anaphylactic reaction, hypocalcaemia, sciatica, nausea, constipation, abdominal discomfort, gastritis,

aspartate aminotransferase increased, rash, eczema, alopecia, lichenoid drug eruption, hypersensitivity vasculitis, pain in extremity, musculoskeletal pain, myalgia, back pain, compression fracture, osteonecrosis of the jaw, atypical femoral fractures, osteonecrosis of the external auditory canal, pyrexia.

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