DARZALEX® 20 mg/ml Concentrate for Solution for Infusion and 1,800 mg Solution for Injection
ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Daratumumab

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): Darzalex SC and IV: ***Newly diagnosed multiple myeloma****:* in combination with lenalidomide/dexamethasone or bortezomib/melphalan/prednisone in adults, ineligible for autologous stem cell transplant; in combination with bortezomib, thalidomide and dexamethasone in adults, eligible for autologous stem cell transplant. ***Relapsed/Refractory multiple myeloma****:* Monotherapy for adults whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on last therapy. In combination with lenalidomide/dexamethasone or bortezomib/dexamethasone in adults who have received ≥ one prior therapy. **Darzalex SC only**: in combination with bortezomib/lenalidomide/dexamethasone in adults with newly diagnosed multiple myeloma; in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor and lenalidomide and were lenalidomide-refractory, or who have received at least two prior therapies that included lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or after the last therapy. ***Smouldering multiple myeloma (SMM):*** **Darzalex SC** as monotherapy in adults at high risk of developing multiple myeloma. ***AL Amyloidosis:*** **Darzalex SC** in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic light chain (AL) amyloidosis.

DOSAGE & ADMINISTRATION: Administration by healthcare professional where resuscitation facilities are available, intravenous (IV) infusion or subcutaneous (SC) injection. For **SC injection,** resuscitation facilities required only for first dose. **Adults:** Recommended **IV dose**: 16 mg/kg body weight. Dilute with sodium chloride 0.9% solution for injection and administer by IV infusion using incremental escalation of infusion rate, only if previous infusion well-tolerated. **SC dose**: inject 15 mL (1,800 mg) Darzalex solution for SC injection into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes according to dosing schedule. Patients > 120 kg, flat-dose 1,800 mg SC, efficacy not established. **SC injection:** no dose adjustments based on body weight recommended. Darzalex solution for SC injection should never be injected into areas where the skin is red, bruised, tender, hard or areas where there are scars, rotate injection site. During treatment with Darzalex SC injection, do not administer other medicinal products for subcutaneous use at the same site as Darzalex. Check the vial labels to ensure that the appropriate formulation (IV or SC formulation) and dose is being given as prescribed. For dose and schedule of medicinal products administered with DARZALEX, refer to SmPC 4.2 and the corresponding SmPC for other products. Administer pre- and post-injection medicinal products to reduce the risk of infusion-related reactions (IRRs). *Recommended concomitant medications for management of infusion/injection-related reactions (IRRs):* administer pre- IV infusion/ SC Injection medicinal products to all patients 1-3 hours prior to every infusion (corticosteroid, antipyretics and antihistamine. For SMM indication a leukotriene inhibitor is also recommended). For **SC injections**, pre-medications can be given orally from the first dose. When dexamethasone is background-regimen specific corticosteroid, this dose will serve as pre-medication on infusion days. If pre-

medication dexamethasone is given on infusion day, do not take additional background regimen specific corticosteroids (e.g. prednisone) on Darzalex administration days. Post- IV infusion/SC injection medicinal products should be administered to reduce the risk of delayed IRRs: administer oral corticosteroid. **SC injections**: if the patient experiences no major IRRs after the first three SC injections, post-injection corticosteroids (excluding any background regimen corticosteroids) may be discontinued. Consider short/long acting bronchodilators and inhaled corticosteroids in patients with history of chronic obstructive pulmonary disorder. **IV Infusion**: Any grade/severity IRRs, interrupt Darzalex immediately and manage symptoms. Re-starting Darzalex IV infusion: reduce infusion rate (refer to SmPC); Grade 4 IRRs (or third occurrence of Grade 3) – permanently discontinue. **IV and SC**: For haematological toxicity dose delay may be required to allow recovery of blood cell counts. No dose reductions of Darzalex recommended. Consider anti-viral prophylaxis for prevention of herpes zoster virus reactivation. **Children:** No data available. **Elderly/Renal impairment/Hepatic impairment:** No dose adjustments.

CONTRAINDICATIONS: Hypersensitivity to active substance or excipients.

SPECIAL WARNINGS & PRECAUTIONS: Please refer to SmPC for information on the following special warnings and precautions: Traceability; Infusion-related reactions, Neutropenia/Thrombocytopenia, Interference with indirect antiglobulin test (indirect Coombs test), Interference with determination of complete response, Hepatitis B virus (HBV) reactivation, Body weight (> 120 kg), Excipients.

SIDE EFFECTS: Very common: IRRs (Darzalex IV), upper respiratory tract infection, COVID-19, pneumonia, bronchitis, neutropenia, thrombocytopenia, anaemia, lymphopenia, leukopenia, decreased appetite, hypokalaemia, insomnia, peripheral neuropathy, headache, paraesthesia, dizziness, hypertension, cough, dyspnoea, constipation, diarrhoea, nausea, vomiting, abdominal pain, rash, musculoskeletal pain, arthralgia, muscle spasms, oedema peripheral, fatigue, pyrexia, asthenia. **SC only**: injection site reactions. **Common:** IRRs (Darzalex SC), urinary tract infection, sepsis, cytomegalovirus infection, hypogammaglobulinemia, hyperglycaemia, hypocalcaemia, dehydration, syncope, atrial fibrillation, pulmonary oedema, pancreatitis, pruritus, chills. **Uncommon:** Hepatitis B Virus reactivation.

Refer to SmPC for further information on side effects.

LEGAL CATEGORY: Prescription only medicine (POM)

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S)

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)
5 ml vial (100 mg daratumumab)	X 1	EU/1/16/1101/001
20 ml vial (400 mg daratumumab)	X 1	EU/1/16/1101/002
15 ml vial (1800 mg daratumumab)	X 1	EU/1/16/1101/004

MARKETING AUTHORISATION HOLDER: Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, Belgium

FURTHER INFORMATION IS AVAILABLE FROM: Janssen Sciences Ireland UC, Barnahely, Ringaskiddy, IRL – Co. Cork P43 FA46

Prescribing information updated: July 2025

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC, a Johnson & Johnson company, on 0044 1494 567447 or at dsafety@its.jnj.com.