IMBRUVICA® 140 mg, 280 mg, 420 mg and 560 mg Film-coated Tablets
ABBREVIATED PRESCRIBING INFORMATION

ACTIVE INGREDIENT: Ibrutinib

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

INDICATIONS: In combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (IMBRUVICA + R-CHOP) alternating with R-DHAP (or R-DHAOx) without IMBRUVICA, followed by IMBRUVICA monotherapy, for adults with previously untreated mantle cell lymphoma (MCL) who would be eligible for autologous stem cell transplantation (ASCT). As a single agent, for adults with relapsed or refractory MCL. As a single agent or in combination with rituximab or obinutuzumab or venetoclax for adults with chronic lymphocytic leukaemia (CLL) who are previously untreated. As a single agent or in combination with bendamustine and rituximab (BR) for adults with CLL who have received ≥ one prior therapy. As a single agent for adults with Waldenström's macroglobulinaemia (WM) who have received ≥ one prior therapy, or first line in patients unsuitable for chemo-immunotherapy. In combination with rituximab for adults with WM.

DOSAGE & ADMINISTRATION: Adults: Orally, once daily, swallowed whole with water. Previously untreated MCL – 560 mg once daily in combination (refer to SmPC) as follows: Part I (6 cycles, each 21 days): Cycles 1, 3, 5: IMBRUVICA (days 1-19) + R-CHOP, Cycles 2, 4, 6: R-DHAP or R-DHAOx (without IMBRUVICA), Part II**:** IMBRUVICA as a single agent, daily for 24 months - treatment should start after recovery of blood counts; rituximab may be added per national treatment guidelines. Relapsed or refractory MCL - 560 mg as a single agent. CLL and WM - 420 mg as single agent or in combination (refer to SmPC). Treatment with IMBRUVICA as a single agent or in combination with anti-CD20 therapy should continue until disease progression or no longer tolerated by the patient. In combination with venetoclax for the treatment of CLL, IMBRUVICA should be administered as a single agent for 3 cycles (1 cycle is 28 days), followed by 12 cycles of IMBRUVICA plus venetoclax. See the venetoclax SmPC for full venetoclax dosing information.
Concomitant strong CYP3A4 inhibitors – reduce dose to 140 mg (or withhold IMBRUVICA for up to 7 days). Concomitant moderate CYP3A4 inhibitors – reduce dose to 280 mg. Withhold IMBRUVICA therapy for any new onset/worsening grade 2 cardiac failure, grade 3 cardiac arrythmias, grade ≥ 3 non-haematological toxicity, grade ≥ 3 neutropenia with infection/fever, or grade 4 haematological toxicities. Refer to SmPC for further information on dose modification and discontinuation recommendations for non-cardiac and cardiac events. **Children:** Not recommended for use in patients ≤ 18 years old. **Elderly:** No dose adjustment required. **Renal impairment:** Mild/moderate - no dose adjustment. Severe – no data; consider benefit/risk and monitor closely. No data with dialysis. **Hepatic impairment:** Mild (Child-Pugh class A) – 280 mg daily; moderate (Child-Pugh class B) – 140 mg daily; severe (Child-Pugh class C) – not recommended. Monitor for toxicities. **Severe cardiac disease:** No clinical data.

CONTRAINDICATIONS: Hypersensitivity to active substance/excipients. St. John's Wort preparations.

SPECIAL WARNINGS & PRECAUTIONS: Please refer to SmPC for information on the following special warnings and precautions: Bleeding-related events; Leukostasis*;* Splenic rupture; Infections; Hepatic events*;* Cytopenias*;* Interstitial Lung Disease (ILD); Cardiac arrhythmias and cardiac failure*;* Cerebrovascular accidents; Tumour lysis syndrome*;* Non-melanoma skin cancer*;* Hypertension*;* Haemophagocytic

lymphohistiocytosis (HLH); Drug-drug interactions; Women of childbearing potential; Excipients with known effect.

SIDE EFFECTS: Very common: Pneumonia, upper respiratory tract infection, skin infection, neutropenia, febrile neutropenia, thrombocytopenia, lymphocytosis, dizziness, headache, peripheral neuropathy, haemorrhage, bruising, hypertension, diarrhoea, vomiting, stomatitis, nausea, constipation, dyspepsia, rash, arthralgia, muscle spasms, musculoskeletal pain, acute kidney injury, pyrexia, oedema peripheral, blood creatinine increased. **Common:** Sepsis, urinary tract infection, sinusitis, non-melanoma skin cancer, basal cell carcinoma, squamous cell carcinoma, leukocytosis, interstitial lung disease, hyperuricaemia, tumour lysis syndrome, vision blurred, cardiac failure, atrial fibrillation, epistaxis, petechiae, urticaria, erythema, onychoclasis. **Uncommon:** Fungal infections (Cryptococcal, Pneumocystis, Aspergillus), hepatitis B reactivation, cerebrovascular accident, transient ischaemic attack, ischaemic stroke, eye haemorrhage, uveitis, ventricular tachyarrhythmia, cardiac arrest, subdural haematoma, hepatic failure, angioedema, panniculitis, neutrophilic dermatoses, pyogenic granuloma, cutaneous vasculitis.

Refer to SmPC for further information on side effects.

LEGAL CATEGORY: Prescription only medicine (POM)

PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S):
140 mg blister pack, 28 tablets, EU/1/14/945/007.
280 mg blister pack, 28 tablets, EU/1/14/945/009.
420 mg blister pack, 28 tablets, EU/1/14/945/011.
560 mg blister pack, 28 tablets, EU/1/14/945/012.

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: October 2025

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events 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.