

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: As a single agent, for adults with relapsed or refractory mantle cell lymphoma (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 \geq one prior therapy. As a single agent for adults with Waldenström's macroglobulinaemia (WM) who have received \geq 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. MCL - 560 mg. CLL and WM -420 mg as single agent or in combination (refer to SmPC). Treatment with IMBRUVICA 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 Summary of Product Characteristics (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 arrhythmias, grade \geq 3 non-haematological toxicity, grade \geq 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 \leq 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, thrombocytopenia, lymphocytosis, dizziness, headache, haemorrhage, bruising, hypertension, diarrhoea, vomiting, stomatitis, nausea, constipation, dyspepsia, rash, arthralgia, muscle spasms, musculoskeletal pain, pyrexia, oedema peripheral, blood creatinine increased. **Common:** Sepsis, urinary tract infection, sinusitis, non-melanoma skin cancer, basal cell carcinoma, squamous cell carcinoma, febrile neutropenia, leukocytosis, interstitial lung disease, hyperuricaemia, peripheral neuropathy, vision blurred, cardiac failure, atrial

fibrillation, epistaxis, petechiae, urticaria, erythema, onychoclasia, acute kidney injury. **Uncommon:** Fungal infections (Cryptococcal, Pneumocystis, Aspergillus), hepatitis B reactivation, tumour lysis syndrome, cerebrovascular accidents, transient ischaemic attack, ischaemic stroke, eye haemorrhage, 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

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: August 2024

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 on 0044 1494 567447 or at dsafety@its.jnj.com.