Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Lenalidomide 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and 25mg Hard capsules Abbreviated Prescribing Information. **Presentation:** Each hard capsule contains lenalidomide hydrochloride hydrate corresponding to 2.5mg, 5mg, 7.5mg, 10mg, 15mg 20mg or 25mg of lenalidomide. **Indications:** As monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation; as combination therapy with dexamethasone or bortezomib and dexamethasone, or melphalan and prednisone for the treatment of adult patients with previously untreated multiple myeloma not eligible for transplant; in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy; in combination with rituximab (anti-CD20 antibody) for the treatment of adult patients with previously treated follicular lymphoma (Grade 1-3a); as monotherapy for the treatment of adult patients with transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate; as monotherapy for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). **Dosage and administration:** Take orally at same time on the scheduled days. Swallow capsule whole, preferably with water, either with/without food. Capsules should not be opened, broken or chewed. Healthcare professionals or caregivers should wear disposable gloves when handling blister or capsule. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Treatment should be supervised by a physician experienced in the use of anti-cancer therapies. Dose is modified based upon clinical and laboratory findings (see SmPC for dose reduction steps). Dose adjustments during treatment and restart of treatment are recommended to manage Grade 3 or 4 thrombocytopenia, neutropenia or other Grade 3 or 4 toxicity related to lenalidomide. Growth factors should be considered in case of neutropenia management. Refer to SmPC for dosing recommendations and adjustments during treatment for all therapeutic indications. *Adults*: newly diagnosed multiple myeloma (NDMM): *Lenalidomide in combination with dexamethasone until disease progression in patients not eligible for transplant:* Lenalidomide treatment must not be started if the ANC is < 1.0 x 10^9/L, and/or platelet counts are < 50 x 10^9/L. *Lenalidomide in combination with bortezomib and dexamethasone followed by lenalidomide and dexamethasone until disease progression in patients not eligible for transplant: Initial treatment:* Lenalidomide in combination with bortezomib and dexamethasone must not be started if the ANC is < 1.0 x 10^9/L, and/or platelet counts are < 50 x 10^9/L. *Continued treatment: Lenalidomide in combination with dexamethasone until progression:* Continue lenalidomide 25mg orally once daily on days 1-21 of repeated 28-day cycles in combination with dexamethasone; *Lenalidomide in combination with melphalan and prednisone followed by lenalidomide maintenance in patients not eligible for transplant;* Lenalidomide treatment must not be started if the ANC is < 1.5 x 10^9/L, and/or platelet counts are < 75 x 10^9/L. *Lenalidomide maintenance in patients who have undergone autologous stem cell transplantation (ASCT):* Lenalidomide maintenance should be initiated after adequate haematologic recovery following ASCT in patients without evidence of progression. Lenalidomide must not be started if the Absolute Neutrophil Count (ANC) is < 1.0 x 10^9/L, and/or platelet counts are < 75 x 10^9/L. *Multiple myeloma with at least one prior therapy:* Lenalidomide treatment must not be started if the ANC < 1.0 x 10^9/L, and/or platelet counts < 75 x 10^9/L or, dependent on bone marrow infiltration by plasma cells, platelet counts < 30 x 10^9/L. *Myelodysplastic syndromes (MDS):* Lenalidomide treatment must not be started if the ANC < 0.5 x 10^9/L and/or platelet counts < 25 x 10^9/L. Patients without at least a minor erythroid response within 4 months of therapy initiation, demonstrated by at least a 50% reduction in transfusion requirements or, if not transfused, a 1g/dl rise in haemoglobin, should discontinue lenalidomide treatment. *Follicular lymphoma (FL):* Lenalidomide treatment must not be started if the ANC is < 1 x 10^9/L, and/or platelet count < 50 x 10^9/L, unless secondary to lymphoma infiltration of bone marrow.*Children*: should not be used. *Elderly:* take care in dose selection and monitor renal function. *Renal impairment:* take care in dose selection and monitor renal function *mild:* no dose adjustment; *moderate or severe:* see SmPC for dose adjustment. *Hepatic impairment:* no dose recommendations. **Contraindications:** Hypersensitivity to active substance or excipients; women who are pregnant; women of childbearing potential unless all conditions of the Pregnancy Prevention Programme are met. **Precautions and warnings:** When lenalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients, including males (refer to SmPC) prior to prescribing. If lenalidomide is taken during pregnancy, a teratogenic effect is expected. Women of childbearing potential must use at least one effective contraception method for at least 4 weeks before therapy, during therapy, and after finishing therapy and dose interruption. Combined oral contraceptive pills are not recommended due to increased risk of venous thromboembolism. Implants and levonorgestrel-releasing intrauterine systems are associated with an increased risk of infection –

prophylactic antibiotics should be considered particularly in patients with neutropenia. Copper-releasing intrauterine devices are not recommended. Medically supervised pregnancy testing should be performed prior to starting treatment and repeated at least every 4 weeks during treatment and 4 weeks after end of treatment. Patients should not donate blood during treatment or for at least 7 days after discontinuation. Myocardial infarction, venous and arterial thromboembolic events has been reported. Patients with known risk factors, including prior thrombosis, should be closely monitored and action taken to minimise all modifiable risk factors. The decision to take antithrombotic prophylactic measures should be considered. If patient experiences any thromboembolic event, treatment must be discontinued and standard anticoagulation therapy started. A complete blood cell count should be performed at baseline and during treatment (see SmPC) to monitor for cytopenias. Evaluate patients for signs and symptoms of underlying cardiopulmonary disease prior to initiating and during lenalidomide treatment. Co-administration with other myelosuppressive agents should be undertaken with caution. Close observation for signs and symptoms of bleeding, including petechiae and epistaxis is recommended. Optimal control of co-morbid conditions influencing thyroid function is recommended and monitored throughout treatment. Caution advised in patients at risk of tumour lysis syndrome (TLS) or tumour flare reaction (TFL). Careful monitoring and evaluation is recommended. All patients receiving lenalidomide treatment for MCL or follicular lymphoma should receive TLS prophylaxis and be well hydrated. Allergic reactions/hypersensitivity reactions and severe skin reactions have been reported – monitor closely. Treatment must be discontinued if angioedema, anaphylactic reaction, exfoliative or bullous rash, Stevens-Johnson Syndrome (SJS), Toxic epidermal necrolysis (TEN) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) is suspected and treatment must not be resumed. Interruption or discontinuation should be considered for other forms of skin reaction depending on severity. Patients who had previous allergic reactions while treated with thalidomide should be monitored closely as possible as cross-reaction has been reported. Patients with a history of severe rash associated with thalidomide treatment should not receive lenalidomide. An increase of second primary malignancies (SPM) has been observed. The risk must be taken into account. Evaluate and monitor patients before and during treatment. Monitoring of liver function is recommended. Patients with known risk factors for infections should be closely monitored. Caution is recommended in patients previously infected with hepatitis B virus – monitor closely. Signs and symptoms for Progressive multifocal leukoencephalopathy (PML) should be monitored. If PML is confirmed, discontinue lenalidomide treatment. The patients' ability to tolerate lenalidomide in combination, with consideration to age, ISS stage III, ECOG PS ≤ 2 or CLcr<60 mL/min should be assessed. Regular monitoring of visual ability is recommended. **Interactions:** Erythropoietic agents or other agents that may increase the risk of thrombosis, should be used with caution. Efficacy of oral contraceptives may be reduced. Close monitoring of warfarin and digoxin concentration is advised. Increased risk of rhabdomyolysis with statins – enhanced clinical and laboratory monitoring is warranted. **Pregnancy and lactation:** Contraindicated in pregnancy. Breast-feeding should be discontinued. **Effects on ability to drive and use machines:** Minor or moderate influence. Caution recommended. **Adverse reactions:** pneumonia, neutropenic infection, lung infection, sepsis, bacteraemia, myelodysplastic syndrome, neutropenia, febrile neutropenia, thrombocytopenia, leukopenia, pancytopenia, hypokalaemia, peripheral neuropathy, pulmonary embolism, deep vein thrombosis, cellulitis, opportunistic infections, enterocolitis infectious, basal cell carcinoma, squamous skin cancer, acute myeloid leukaemia, T-cell type acute leukaemia, Tumour lysis syndrome, haemorrhagic disorder, haemolytic anaemia, autoimmune haemolytic anaemia, haemolysis, hypersensitivity, diabetes mellitus, cerebrovascular accident, intracranial haemorrhage, transient ischaemic attack, cerebral ischaemia, cataract, blindness, deafness (including hypoacusis), atrial fibrillation, bradycardia, myocardial infarction (including acute), congestive cardiac failure, cardiac failure, myocardial ischaemia, QT prolongation, arrhythmia, venous thromboembolic events, intracranial venous sinus thrombosis, respiratory distress, hypoxia, gastrointestinal haemorrhage (including rectal haemorrhage), haemorrhoidal haemorrhage, small intestinal obstruction, peptic ulcer haemorrhage, cholestasis, hepatotoxicity, hepatocellular injury, hepatic failure, drug reaction with eosinophilia and systemic symptoms, renal failure (including acute), renal tubular necrosis, acquired Fanconi syndrome, tumour flare, acute kidney injury, hepatitis B reactivation, acquired haemophilia, solid organ transplant rejection, pulmonary hypertension, pancreatitis, gastrointestinal perforation (including diverticular, intestinal and large intestine perforations, acute hepatic failure, cytolytic hepatitis, cholestatic hepatitis, mixed cytolytic/cholestatic hepatitis, Stevens-Johnson Syndrome, Toxic epidermal necrolysis. *Very Common***:** respiratory tract infection, bronchitis, influenza, gastroenteritis, sinusitis, nasopharyngitis, rhinitis**,** anaemia, lymphopenia, paraesthesia, cough, dyspnoea, rhinorrhoea, diarrhoea, constipation, abdominal pain, nausea, abnormal liver function tests, rash, dry skin, muscle spasms, fatigue, asthenia, pyrexia, bacterial, viral and fungal infections (including opportunistic infections, pharyngitis, hyper/hypoglycaemia, hypocalcaemia, hyponatraemia, dehydration, decreased appetite, weight decreased, depression, insomnia, peripheral neuropathies, paraesthesia, dizziness, tremor, dysgeusia, headache, blurred vision, epistaxis, cough, vomiting, dyspepsia, dry mouth, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, rashes, pruritus, muscular weakness, muscle spasms, bone pain,

musculoskeletal and connective tissue pain and discomfort (including back pain), pain in extremity, myalgia, arthralgia, oedema (including peripheral), influenza like illness syndrome, blood alkaline phosphatase increased, decreased appetite, *Common:* infection, lower respiratory tract infection, herpes zoster, hypothyroidism, hyperuricaemia, gout, hypomagnesaemia, hypercalcaemia, ataxia, balance impaired, syncope, neuralgia, dysaesthesia, reduced visual acuity, tinnitus, tachycardia, hyper/hypotension, ecchymosis, vasculitis, dysphonia, pleuritic pain, gingival bleeding, dysphagia, hyperbilirubinaemia, urticaria, hyperhidrosis, skin hyperpigmentation, eczema, erythema, skin discolouration, photosensitivity reaction, joint swelling, haematuria, urinary retention/incontinence, erectile dysfunction, chest pain, lethargy, c-reactive protein increased, fall, contusion, hypophosphataemia, oropharyngeal pain, night sweats, neck pain, malaise, chills, blood bilirubin increased. Consult the SmPC in relation to other side effects. **Overdose:** Supportive care is advised. **Price:** Pack Quantity: 21 tablets (all strengths); 2.5mg (Pack Qty 7): £1027.80, 2.5mg (Pack Qty 21): £3083.40; 5mg: £3213.00; 7.5mg: £3307.50; 10mg: £3402.00; 15mg: £3572.10; 20mg: £3751.65; 25mg: £3931.20. **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/2182-88. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00066. **Date of Preparation**: January 2022.