

PRESCRIBING INFORMATION

IMFINZI® ▼ (durvalumab) 50mg/ml Solution for Infusion

Consult Summary of Product Characteristics before prescribing.

Indication: IMFINZI as monotherapy is indicated for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on $\geq 1\%$ of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy. IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC).

Presentation: Each ml of concentrate for solution for infusion contains 50mg durvalumab.

Dosage and administration: Treatment must be initiated and supervised by a physician experienced in the treatment of cancer. Patients with locally advanced NSCLC should be evaluated for treatment based on the tumour expression of PD-L1 confirmed by a validated test. The recommended dose for IMFINZI monotherapy is 10 mg/kg administered as an intravenous infusion over 1 hour every 2 weeks or 1500mg every 4 weeks, until disease progression, unacceptable toxicity, or a maximum of 12 months. Patients with a body weight of 30kg or less must receive weight-based dosing, equivalent to IMFINZI 10 mg/kg every 2 weeks or 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30kg. The recommended dose for IMFINZI combination is 1500mg, administered as an intravenous infusion over 1 hour, in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 1500mg every 4 weeks as monotherapy, until disease progression or unacceptable toxicity. Dose escalation or reduction is not recommended. Dose withholding or discontinuation may be required based on individual safety and tolerability. **Suspected immune-mediated adverse reactions:** Adequate evaluation should be performed to confirm aetiology or exclude alternate aetiologies. Consider increasing dose of corticosteroids and/or using additional systemic immunosuppressants if there is worsening or no improvement. Upon improvement to \leq Grade 1, corticosteroid taper should be initiated and continued over at least 1 month. After withhold, IMFINZI can be resumed within 12 weeks if the adverse reactions improved to \leq Grade 1 and the corticosteroid dose has been reduced to ≤ 10 mg prednisone or equivalent per day. IMFINZI should be permanently discontinued for recurrent Grade 3 or 4 (severe or life-threatening) immune-mediated adverse reactions. **Non-immune-mediated adverse reactions:** Consider withholding IMFINZI for Grade 2 and 3 adverse reactions until \leq Grade 1 or baseline. IMFINZI should be discontinued for Grade 4 adverse reactions. **Special populations:** **Elderly:** No dose adjustment is required for elderly patients (≥ 65 years of age). **Renal impairment:** No dose adjustment is recommended in patients with mild or moderate renal impairment. Data from patients with severe renal impairment are too limited to draw conclusions on this population. **Hepatic impairment:** Data from patients with moderate and severe hepatic impairment are limited. Due to minor involvement of hepatic processes in the clearance of durvalumab no dose adjustment of IMFINZI is recommended for patients with hepatic impairment as no difference in exposure is expected.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and precautions: **Traceability:** In order to improve the traceability of biological medicinal products, the tradename and the batch number of the administered product should be clearly recorded. **Immune-mediated pneumonitis:** Monitor for signs and symptoms of pneumonitis or radiation pneumonitis. Suspected pneumonitis should be confirmed with radiographic imaging and other infectious and disease-related aetiologies excluded. **Immune-mediated hepatitis:** Monitor for abnormal liver tests prior to and periodically during treatment with IMFINZI, and as indicated based on clinical evaluation. **Immune-mediated colitis:** Monitor for signs and symptoms of colitis or diarrhoea. **Immune-mediated endocrinopathies:** Monitor for abnormal thyroid function tests prior to and periodically during treatment and as indicated based on clinical evaluation. **Immune-mediated adrenal insufficiency:** Monitor for clinical signs and symptoms of adrenal insufficiency. **Immune-mediated type 1 diabetes mellitus:** Monitor for clinical signs and symptoms of type 1 diabetes mellitus. **Immune-mediated hypophysitis/hypopituitarism:** Monitor for clinical signs and symptoms of hypophysitis or hypopituitarism. **Immune-mediated nephritis:** Monitor for abnormal renal function tests prior to and periodically during treatment with IMFINZI. **Immune-mediated rash:** Events of Stevens-Johnson Syndrome or toxic epidermal necrolysis have been reported in patients treated with PD-1 inhibitors. Patients should be monitored for signs and symptoms of rash or dermatitis (including pemphigoid). **Other immune-mediated adverse reactions:** Myasthenia gravis, myocarditis, myositis, polymyositis, meningitis, encephalitis, Guillain-Barre syndrome and immune thrombocytopenia have been observed. Events of pancreatitis have been reported in patients in the clinical study programme. Monitor for signs and symptoms. **Infusion related reactions:** Monitor for signs and symptoms of infusion related reactions. **All immune-mediated adverse events should be managed as recommended in Section 4.2 of the SmPC.** **Patients excluded from clinical trials:** Patients with: a baseline ECOG performance score ≥ 2 ; active or prior documented autoimmune disease within 2 years of initiation of the study; a history of immunodeficiency; a history of severe immune-mediated adverse reactions; medical conditions that required systemic immunosuppression, except physiological dose of systemic corticosteroids (≤ 10 mg/day prednisone or equivalent); uncontrolled intercurrent illnesses; active tuberculosis or hepatitis B or C or HIV infection or patients receiving live attenuated vaccine within 30 days before or after the start of IMFINZI. Durvalumab should be used with caution in these populations after careful consideration of the potential benefit/risk on an individual basis. The safety of concurrent prophylactic cranial irradiation (PCI) with IMFINZI in patients with ES-SCLC is unknown.

Drug interactions: The use of systemic corticosteroids or immunosuppressants before starting durvalumab, except physiological dose of systemic corticosteroids (≤ 10 mg/day prednisone or equivalent), is not recommended because of their potential interference with the pharmacodynamic activity and efficacy of durvalumab. However, systemic corticosteroids or other immunosuppressants can be used after starting durvalumab to treat immune-related adverse reactions.

Pregnancy and lactation: Durvalumab may cause foetal harm when administered to a pregnant woman and is not recommended during pregnancy and in women of childbearing potential not using effective contraception during treatment and for at least 3 months after the last dose. A decision must be made whether to discontinue breast feeding or to discontinue or abstain from durvalumab therapy taking into

account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Undesirable events: Consult SmPC for full list of adverse events. **IMFINZI Monotherapy: Very common ($\geq 1/10$; any grades):** Upper respiratory tract infections, hypothyroidism, cough/productive cough, diarrhoea, abdominal pain, rash, pruritus, pyrexia. **Common ($\geq 1/100$ to $< 1/10$; any grades):** Pneumonia, dental and oral soft tissue infections, oral candidiasis, influenza, hyperthyroidism, pneumonitis, dysphonia, aspartate aminotransferase increased or alanine aminotransferase increased, night sweats, myalgia, blood creatinine increased, dysuria, peripheral oedema, infusion related reaction. **Uncommon ($\geq 1/1,000$ to $< 1/100$; any grades):** Thyroiditis, adrenal insufficiency, interstitial lung disease, colitis, dermatitis hepatitis, myositis, nephritis. **Rare ($\geq 1/10,000$ to $< 1/1000$; any grades):** Type I diabetes mellitus, hypophysitis/hypopituitarism, diabetes insipidus, myocarditis, meningitis, polymyositis, pemphigoid, myasthenia gravis, immune thrombocytopenia. **Not known:** Noninfective encephalitis, Guillain-Barre syndrome. **IMFINZI Combined with Chemotherapy: Very common ($\geq 1/10$; any grades):** Neutropenia, anaemia, thrombocytopenia, leukopenia, decreased appetite, cough/productive cough, nausea, constipation, vomiting, alopecia, fatigue. **Common ($\geq 1/100$ to $< 1/10$; any grades):** Upper respiratory tract infections, pneumonia, dental and oral soft tissue infections, febrile neutropenia, pancytopenia, hypothyroidism, hyperthyroidism, thyroiditis, adrenal insufficiency, pneumonitis, diarrhoea, abdominal pain, stomatitis, aspartate aminotransferase increased or alanine aminotransferase increased, hepatitis, rash, pruritus, dermatitis, myalgia, blood creatinine increased, dysuria, pyrexia, peripheral oedema, infusion-related reaction. **Uncommon ($\geq 1/1,000$ to $< 1/100$; any grades):** Oral candidiasis, influenza, Type I diabetes mellitus, dysphonia, interstitial lung disease, colitis, night sweats.

Legal category: POM.

Marketing authorisation number: EU/1/18/1322/001; EU/1/18/1322/002.

Presentation & Basic NHS cost: One 2.4mL vial (120mg durvalumab), £592; One 10mL vial (500mg durvalumab), £2,466.

Marketing Authorisation Holder: AstraZeneca AB, SE-151 85, Södertälje, Sweden.

Further information is available from: AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.

IMFINZI® is a registered trade mark of the AstraZeneca group of companies.

Date of preparation: 02/2021

ONC 21 0014

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting <https://contactazmedical.astrazeneca.com> or by calling 0800 783 0033.