**Prescribing Information: Dupixent (dupilumab) solution for injection in a pre-filled syringe or pen (Chronic Obstructive Pulmonary Disease (COPD))**

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

**Presentations:** Dupixent 300 mg solution for injection in a pre-filled syringe or pen, containing 300 mg of dupilumab in 2 ml solution (150 mg/ml).

**Indication:** Dupixent is indicated in adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate.

**Dosage and Administration:** The recommended dose of dupilumab for adult patients is 300 mg given every other week. Dupilumab is intended for long-term treatment. Dosing beyond 52 weeks has not been studied. Consideration should be given to discontinuing treatment in patients who have shown no response after 52 weeks of treatment for COPD.

***Missed dose:*** See SmPC for more information on missed dose.

**Special populations:** *Elderly (≥ 65 years):* No dose adjustment recommended. *Renal impairment:* No dose adjustment in patients with mild or moderate renal impairment. Very limited data available in patients with severe renal impairment. *Body weight:* No dose adjustment for body weight is recommended for patients. *Hepatic impairment:* No data available. *Paediatric population:* The safety and efficacy of dupilumab in children with COPD below the age of 18 years have not been established. No data are available.

***Method of administration:*** The Dupixent pre-filled pen and pre-filled syringe is for use in adults.

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

**Warnings and Precautions:** ***Acute asthma or COPD exacerbations:*** Dupixent should not be used to treat acute symptoms or acute exacerbations of asthma or COPD; acute bronchospasm or status asthmaticus. ***Corticosteroids:*** Systemic, topical, or inhaled corticosteroids should not be discontinued abruptly upon initiation of therapy with dupilumab. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy. Biomarkers of type 2 inflammation may be suppressed by systemic corticosteroid use. This should be taken into consideration to determine type 2 status in patients taking oral corticosteroids. ***Hypersensitivity:*** If a systemic hypersensitivity reaction (immediate or delayed) occurs, administration of Dupixent should be discontinued immediately and appropriate therapy initiated. Anaphylactic reactions and angioedema have occurred from minutes to up to seven days. ***Eosinophilic conditions:*** Cases of eosinophilic pneumonia and vasculitis, consistent with eosinophilic granulomatosis with polyangiitis (EGPA) have been reported. Physicians should be alert to vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients with eosinophilia. Patients may present with serious systemic eosinophilia sometimes presenting with clinical features of eosinophilic pneumonia or vasculitis consistent with eosinophilic granulomatosis with polyangiitis. Often these conditions are treated with systemic corticosteroid therapy. These events usually, but not always, may be associated with the reduction of oral corticosteroid therapy. ***Helminth infection:*** Patients with pre-existing helminth infections should be treated before initiating Dupixent. If patients become infected while receiving treatment with Dupixent and do not respond to anti-helminth treatment, treatment with Dupixent should be discontinued until infection resolves. ***Conjunctivitis, dry eye and keratitis related events:*** Patients should be advised to promptly report new onset or worsening eye symptoms to their healthcare provider. Sudden changes in vision or significant eye pain that does not settle warrant urgent review. Patients treated with Dupixent who develop conjunctivitis or dry eye that does not resolve following standard treatment or signs and symptoms suggestive of keratitis should undergo ophthalmological examination, as appropriate. ***Patients with comorbid asthma:*** Patients on Dupixent who also have comorbid asthma should not adjust or stop their asthma treatments without consultation with their physicians. Patients with comorbid asthma should be monitored carefully following discontinuation of Dupixent. ***Vaccinations:*** Concurrent use of live and live attenuated vaccines with Dupixent should be avoided as clinical safety and efficacy have not been established. ***Interactions:*** Patients receiving Dupixent may receive concurrent inactive or non-live vaccinations. ***Fertility, pregnancy and lactation:*** Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. There are limited data from the use of Dupixent in pregnant women. Dupixent should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. It is unknown whether Dupixent is excreted in human milk or absorbed systemically after ingestion.

**Adverse Reactions:** ***Common (≥1/100 to <1/10):*** Arthralgia, conjunctivitis, conjunctivitis allergic, eosinophilia, injection site reactions (erythema, oedema, pruritis, pain, swelling and bruising), oral herpes. ***Uncommon (≥ 1/1,000 to < 1/100):*** Angioedema, blepharitis, dry eye, eye pruritis, facial rash, keratitis. ***Rare (≥ 1/10,000 to < 1/1,000):*** Anaphylactic reaction, serum sickness reaction, serum sickness-like reaction, ulcerative keratitis. Eye disorders and oral herpes occurred predominantly in atopic dermatitis studies. Additional adverse reactions of injection site induration, injection site rash, and injection site dermatitis were reported in COPD. ***Serious adverse reactions:*** eczema herpeticum and immunogenicity have also been reported. Prescribers should consult the SmPC in relation to other adverse reactions.

**Legal Classification:** POM. **List Price:** 4 week pack containing 2 x pre-filled syringes or pens: £1,264.89. **Marketing Authorisation Holder:** Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. **Marketing Authorisation Numbers**: 2 x 300 mg pre-filled syringe: PLGB 04425/0820. 2 x 300 mg pre-filled pen: PLGB 04425/0771. **Further information is available from:** Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com. **Date of Preparation**: September 2024. **Document Number:** MAT-XU-2402527(v1.0)

**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 the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UKdrugsafety@sanofi.com**